BIOTECHNOLOGY

Industrial College of the Armed Forces
Industry Studies 2005

~~~~~~

ABSTRACT:

The United States biotechnology industry has grown tremendously since 1992, with revenues increasing from $8 billion in 1992 to $39.2 billion in 2003. As a result, biotechnology has revolutionized the way scientists view living matter—their research and development efforts have led to the commercialization of many diverse products which have dramatically improved human and animal health, the world's food supply, and the quality of the environment. These successful applications of biotechnology are now viewed by private sector companies—as well as governments throughout the world—as being the catalysts of long-term economic growth, prosperity, and security. However, the United States, considered the current world leader in biotechnology, is being challenged by Asia for technological preeminence in this field. No longer content to dominate labor-intensive manufacturing, Asian governments are actively promoting biotechnology, nanotechnology, and information technology, and envision themselves becoming world leaders in these technologies—three areas that are likely to generate the next wave of global technological innovation. This report summarizes the current state-of-the-art in biotechnology—along with its economic and national security implications—and examines biotechnology in the broader global context.

Seminar Members:

Ms. Angie Annaballi, Dept of the Air Force

Ms. Jill Beaver, Dept of the Air Force

LTC John Collie, U.S. Army

LTC Rafael DeJesus, U.S. Army

COL Jiri Gajdos, International Fellow, Czech Republic

Dr. Dave Jerome, Office of the Secretary of Defense

Lt Col Stewart LeBlanc, U.S. Air Force Reserve

Ms. Linda Ngo, Missile Defense Agency

CDR Chris Ray, U.S. Navy

Ms. Cecelia Royster, Dept of Homeland Security, U.S. Coast Guard

Lt Col Mike Schalck, U.S. Air Force
~~~~~~

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
2005	**N/A**	**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Biotechnology	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **The Industrial College of the Armed Forces National Defense University Fort McNair Washigton, DC 20319-5062**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**SAR**	**59**	

Mr. Howard Seamens, Defense Information Systems Agency

Mr. Jeffery Shelton, Dept of the Air Force

CAPT Scott Stearney, U.S. Navy

Mr. David Weekman, U.S. Dept of State

COL Steve Zotti, U.S. Marine Corps

Dr. Joseph E. Goldberg, faculty

COL Paul Bartone, U.S. Army, faculty

Col Christina Lafferty, U.S. Air Force Reserve, faculty

Mr. Bill Ortman, Central Intelligence Agency, faculty

ORGANIZATIONS VISITED OR BRIEFING ICAF:

Domestic (Georgia, Maryland, Massachusetts, Virginia, and Washington DC)

Applied Phytogenetics Inc., Athens, GA

Avant Immunotherapeutics, Needham, MA

Booze Allen Hamilton, Falls Church, VA

Center for Disease Control and Prevention, Atlanta, GA

Central Intelligence Agency, McClean, VA

Charles River Laboratories, Inc., Wilmington, MA

Delegation of the European Commission, Washington, DC

Genzyme Corporation, Boston, MA

GTC Biotherapeutics, Inc., Framingham, MA

Harvard Stem Cell Research Institute, Harvard Medical School, Boston, MA

Hemodyne, Inc., Richmond, VA

Human Genome Sciences, Rockville, MD

MedImmune Inc., Gaithersburg, MD

National Institutes of Health, Washington, DC

National Science Foundation, Arlington, VA

Novartis, Boston, MA

Office of Net Assessment, Office of the Secretary of Defense, Washington, DC

State of Maryland, Dept of Business and Economic Development, Annapolis, MD

The Broad Institute for Biomedical Research, Cambridge, MA

U.S. Armed Forces Pathology Laboratory, Rockville, MD

U.S. Army Medical Research & Materiel Command, Fort Detrick, MD

U.S. Army Medical Research Institute for Infectious Diseases, Fort Detrick, MD

U.S. Department of Agriculture, Agricultural Research Service, Beltsville, MD

U. S. Department of State, Washington, DC

Walter Reed Institute of Research, Silver Spring, MD

International (Hong Kong; Guangzhou, China; Singapore)

American Chamber of Commerce, Hong Kong

Biopolis, Singapore

Center for Stem Cell Biology and Tissue Engineering, Sun Yat-Sen University, Guangzhou, China

Chinese University of Hong Kong, Prince of Wales Hospital

CK LifeSciences International, Inc., Hong Kong

CordLife Pte. Ltd., Singapore

Cosmogen Biotech Co., Ltd., Shenzhen, China

Economic Development Board, Singapore

Genome Institute of Singapore

Hong Kong Institute of Biotechnology Ltd

JTC Corporation, Singapore

Novartis Institute for Tropical Diseases, Singapore

Sibiono Genetech Co., Ltd., Shenzhen, China

University of Hong Kong

U.S. Consulate General, Hong Kong

INTRODUCTION:

"Biotechnology will be essential to national long-term economic growth and leadership. From job creation to revenue generation, strength in biotech will be a core building block of America's national competitiveness in the 21st century."

Excerpt from, "A Survey of the Use of Biotechnology in U.S. Industry," United States Department of Commerce, October, 2003.

~~~~~~

This industry study report provides an executive assessment of the biotechnology industry, and outlines its current status—to include such far ranging issues as bioethics, government regulation, intellectual property, the implications of nanotechnology, biodefense, the science and technology workforce, agriculture and genetically-modified foods, the pharmaceutical industry, biotechnology in Asia, as well as other relevant and compelling issues for the industry.

The biotechnology industry has grown tremendously since 1992, with revenues increasing from $8 billion in 1992 to $39.2 billion in 2003 (see Table 1). The industry is quite diverse; for example, molecular genetics provide products as varied as pharmaceuticals and motor fuels, while nanotechnology brings new capabilities to bone and tissue repair. The United States (U.S.) Office of Technology Assessment defined biotechnology (the name is typically foreshortened to "biotech") in 1991 as, "…any technique that uses a living organism, or parts of organisms, to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses."[1] More recently, it has been defined as, "…engineering problems associated with the production and processing of substances obtained through the application of principles and techniques of modern molecular biology."[2] The Biotechnology Industry Organization, which represents a wide range of business interests within the industry, has members in the agriculture, medicine, and animal science industries.[3] As of December 2003, the U.S. biotech industry employed 198,300 people, and is one of the most research-intensive industries in the world, spending $17.9 billion on research and development. The top eight ranked biotech companies spent an average of $104,000 per employee on R&D in 2003, and the U.S. Patent and Trademark Office granted almost 8000 patents in 2002. There are 1,473 biotech companies in the U.S., of which 314 are publicly held, with market capitalization (the total value of publicly-traded U.S. biotech companies at market prices) at $311 billion as of mid-March 2004.[4]

Table 1. U.S. Biotechnology Industry Statistics: 1994–2003 (U.S. dollars in billions).

Year	2003	2002	2001	2000	1999	1998	1997	1996	1995	1994
Sales*	28.4	24.3	21.4	19.3	16.1	14.5	13	10.8	9.3	7.7
Revenues	39.2	29.6	29.6	26.7	22.3	20.2	17.4	14.6	12.7	11.2
R&D Expense	17.9	20.5	15.7	14.2	10.7	10.6	9.0	7.9	7.7	7.0
Net Loss	5.4	9.4	4.6	5.6	4.4	4.1	4.5	4.6	4.1	3.6
No. of Public Companies	314	318	342	339	300	316	317	294	260	265
No. of Companies	1,473	1,466	1,457	1,379	1,273	1,311	1,274	1,287	1,308	1,311
Employees	198,300	194,600	191,000	174,000	162,000	155,000	141,000	118,000	108,000	103,000

Sources: Ernst & Young LLP, annual biotechnology industry reports, 1993–2004. Financial data based primarily on fiscal-year financial statements of publicly traded companies.
~~~~~~

THE INDUSTRY DEFINED:

While biotechnology has been practiced for the last 10,000 years, the term itself was first found in print in 1919.[5] However, today's biotech economic sector is more often associated with the technological successes of the past two decades. This is the time period where scientists have been able to manipulate organisms at their genetic level in order to solve macro problems.

Biotechnology is expected to increase productivity for many industries—its impact on the economy is likely to be similar to that the information technology (IT) has had. In fact, with the specificity, precision, and predictability biotech can bring to an industry, perhaps it can even surpass the productivity gains of the IT revolution. When this productivity is coupled with the world's demographic trends of an aging, longer-living population in the richest countries—and the growing populations in the poorest—the sector should continue to demonstrate strong economic growth far into the future. Simply put, biotechnology has the potential to fuel the next economic revolution.

The U.S. holds a significant advantage in the biotechnology sector (see Table 2). Because of the tremendous potential for economic growth, many countries are investing to cash in on these anticipated future benefits.

Table 2. International Industry Profiles (As of 2002).

	Global	U.S.	Europe	Canada	Asia Pacific
Public Co. Data					
Revenues ($M)	41,369	30,266	8,262	1,466	1,375
R&D Expense ($M)	22,012	16,272	4,989	555	197
Net Income ($M)	-12,483	-9,378	-2763	-263	-79
Number of Employees	193,753	142,900	33,304	7,785	9,764
Number of companies					
Public	613	318	102	85	108
Private	3,749	1,148	1,776	332	493
Total	4,362	1,466	1,878	417	601

Source: Ernst and Young Report, "Global Biotech at a Glance."

While biotechnology certainly has tremendous economic potential, there are also a few causes for concern. Continued access to sufficient capital and labor is challenging, especially for smaller firms. The costs in time and resources, quantity, and quality of government regulation are areas of friction and uncertainty. Within the U.S., the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture all regulate biotech; however, international standards do not exist for biotech. Unfortunately, the lack of sufficient intellectual property (IP) protection outside of the U.S. remains a serious concern to the industry. Increased competition, drug reimportation, biogenerics, and price controls are also likely to have negative impacts on future economic growth.[6] Additionally, there are concerns over whether a sufficient number of qualified scientific personnel exist to maintain U.S. competitive advantage in biotech.

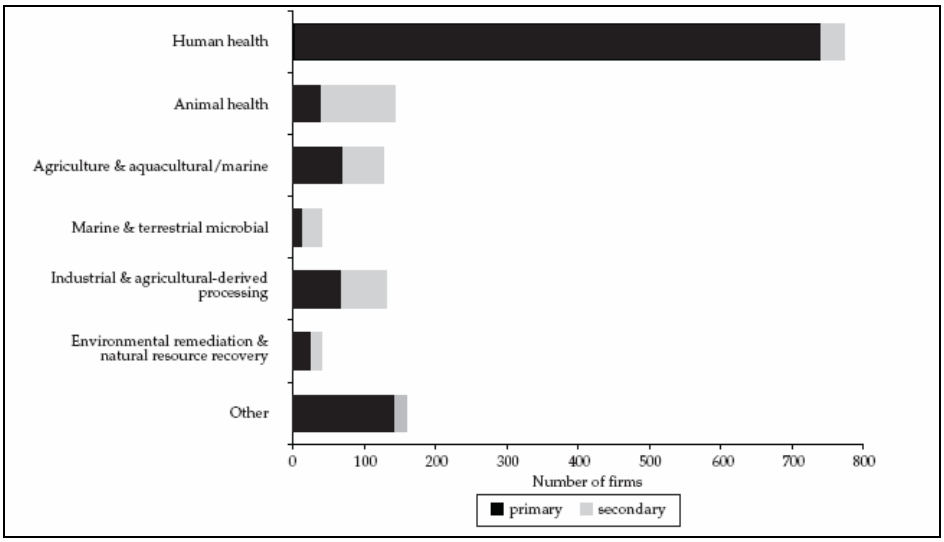
Industry Measurement & Trends. The biotech sector has experienced growth in economic and scientific applications throughout the 1990s and into this century. This growth can be quantified in many ways, demonstrating the rapid industry evolution that is underway. First,

U.S. revenues have increased from $8 billion in 1992 to $39.2 billion in 2003. That is nearly five fold from 1992 to 2002 with approximately 20% growth for the last three years. From 2001 to 2002 the growth in net sales for biotech firms was 10% as compared to 6% for the total U.S. market. Since 1982, when the FDA approved the first biotech drug or vaccine for public use, there have been approximately 285 approvals. There are currently more than 370 biotech drug products and vaccines in clinical trials targeting over 200 diseases.[7] This large number of drugs awaiting approval represents both growth in the sector, as well as the extended amount of time required for drug testing and approval. Furthermore, there are over 800 experimental medications in development.[8]

In the last quarter of 2002, respondents to a Department of Commerce survey indicated that they had pending U.S. patent applications for 33,131 new biotech-related products or processes, compared to 23,992 current U.S. biotech-related patents in their portfolios. Other survey data show that recent discovery, development, and application of biotechnologies are not only creating entirely new types of products and services, but that biotech processes and products are now applied in all types of manufacturing, agriculture, aquaculture, and even at the microbial and nanoscales.[9]

In 2002, the Department of Commerce divided the biotech sector into eight categories for their industry survey (see Figure 1 below): human health; animal health; agricultural and aquaculture/marine; marine and terrestrial microbial; industrial and agriculture-derived processing; environmental remediation; natural resource recovery; and "other". In the survey of biotech industries, more than 75% of all respondents (780) selected "human health" as their primary or secondary application focus, while 12% to 14% of respondents chose one of three other categories—"animal health," "agriculture and aquaculture," or "industrial and agricultural-derived processing"—and 4% to 5% chose either "marine and terrestrial microbial" or "environmental remediation" or "natural resource recovery." Sixteen percent of respondents (160) indicated "other" biotechnology applications as their business focus. Many of these companies develop and market tools to support biotech research and development.[10] As the sector grows and evolves into other industries in the future, this number of divisions is likely to grow.

Figure 1. Biotech Industry Sectors.



Source: U.S. Department of Commerce Technology Administration and Bureau of Industry and Security, "*Critical Assessment of Technology in U.S. Industry*," p. vii, August 2002.

While the "average" biotechnology company is small, private, and unprofitable, several are large multinational corporations with products generating huge revenues and the financial standing of top pharmaceutical firms. For example, the top 10 biotech firms in terms of sales posted around 50% of the revenues from the entire sector. The pharmaceutical industry is dominated by a shrinking group of large, global corporations that continue to merge with or acquire one another in an effort to create mass, reach more markets, enhance product pipelines, and increase in-house research capabilities. The significant growth in the size of participants in the closely-tied biotech and pharmaceutical segments is generating new opportunities as outsourcing activities create demand for specialized laboratory and testing facilities and IT providers.[11]

The human disease and genomics areas of biotechnology typically get the majority of the press and prestige; meanwhile, the field of agricultural biotech has quietly become very robust. Transgenic crops—engineered to withstand weather and insects, have existed for more than a decade. Significant acreage is farmed utilizing genetically engineered or modified plants, fertilizers, and seeds. The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) reported that biotech crop plantings increased 20 % globally from 2003-2004.[12] However, the expanding production and exporting of these crops has caused concern over the safety of the food supply, as well as any long term problems associated with consuming genetically-engineered products. Nonetheless, it would seem that there will continue to be great potential for economic growth in this sector, as these unsubstantiated political concerns are allayed over time.

INDUSTRY CHALLENGES:

In the Department of Commerce survey, a majority of biotech firms identified some type of impediment to the advancement of their research or product commercialization. Three of the impediments that were most cited are: regulatory approval process and costs (59%), research costs, and access to start-up capital (53% each). Firms working in the area of Agri/Aquaculture and Marine biotechnology are concerned about unfair foreign laws and public acceptance concerning ethical considerations. Companies engaged in environmental remediation and natural resource recovery applications are most concerned with antiquated rules and regulations, and unfair U.S. laws.[13]

A major area of controversy, public debate, and barriers surrounds the ethical application of biotechnology. Currently, political, religious, and bioethics groups are trying to control the exploitation of embryonic stem cells. On August 9, 2001, President Bush placed limitations on stem cell research programs with only 78 stem cell lines worldwide meeting eligibility criteria for U.S. federal funding. Of those lines, 51 were either developed by foreign institutions and/or foreign institutions retain the intellectual property rights associated with the lines.[14] Federal funding is very important to scientific research, as investors are currently more focused on financing late product development to minimize their exposure to risk. Without government funding, U.S. scientific research on embryonic stem cells has already fallen behind that of countries that support this type effort, such as South Korea, China, Hong Kong, and Singapore.

Access to Capital. Among all but the very largest firms, access to capital is a major challenge. Smaller firms (those with 500 or fewer employees) are more reliant on venture and angel capital as important sources of funds for their research and development activities. Federal and state government loans and grants are very important. For reasons discussed below, increased government support for basic research is imperative for continued U.S. competitive advantage.

Although the amount of venture capital invested in biotechnology firms declined in both 2001 and 2002, biotech firms received an increasing percentage of venture capital funds. The stage

at which investors support biotech firms is important—most venture capital money is flowing to late-stage product development and less to technology platforms that may be used to develop multiple therapeutics. However, the focus on quickly putting "product on market" is having a negative impact on R&D and innovation within the industry.

In addition, there is intense pressure to get products developed, through testing and approval, and to the market.[15] The recent backtracking by companies and regulators on previously approved drugs is indicative of this serious problem. As a result of these drugs being pulled from the marketplace, the public's perception of the industry and the regulators is at an all time low. The drug industry spent $18.5 billion on marketing last year to the public and medical professionals, which has added to the public criticism. The FDA is under scrutiny as well, accused of placing priority on new drug approvals "funded by the industry" before drug safety. There are currently several bills before Congress to improve drug-safety monitoring.[16]

Intellectual Property (IP). Intellectual property rights—through the patent process—are the engines providing investment funding for biotech R&D. However, patent fees, the patent approval process, and patent rights held by third parties are serious barriers to getting a product to market. Managing IP rights imposes significant complexity and costs on smaller research and development firms.[17] Ongoing patent litigation has special significance for the whole industry, not just the individual companies involved. Generic drug makers are challenging companies in court over three blockbuster drugs. These lawsuits question the original "composition of matter" patents on products, not just the industry's efforts to spin out protection for a few more years of profit. If any one of these decisions were to go against the big companies, it would affect the whole industry.[18]

Several developments in IP have increased the time and resources required to continue research and development efforts, placing a drag on innovation. As entities aggressively pursue protection under U.S. laws, researchers are often required to make agreements with other patent holders to access necessary technology or to form collaborative research and business teams. At the same time, contests for IP rights have become more competitive and increased the number of legal claims, counterclaims, and infringement suits. More broadly, the way in which long-standing IP laws intersect with new biotech-related products and processes uncovered through research and development is a matter of growing controversy. The products of modern genetic research may be considered, depending on their application, either as revealed aspects of nature (which generally are not protected by U.S. patent law) or as inventions and useful devices (which are protected).[19]

A more balanced IP protection system is required. A system that provides market incentives that can facilitate research, but not restrict dissemination, hinder the circulation of ideas, or promote ownership such that the use of underlying scientific and technological advances is slowed. This updated system should exclude basic research from patent protection to encourage innovation. The present legal debate on patent policy and biotech research and development, and the lack of consensus on viable solutions, create uncertainties for biotech businesses. Evidence indicates that investment in biotechnology firms is particularly sensitive to capital and equity markets' perceptions of national patent policy.[20]

Workforce. The population of companies engaged in biotechnology is dynamic and growth in the biotechnology-related workforce has been vigorous, averaging 12.3% annually for 2000–2002. Companies with 50 to 499 employees experienced the fastest growth, with an annual increase of 17.3%, while growth among larger responding firms was 6.2%. These figures compare to essentially no growth in U.S. non-farm payroll employment during this same period. Smaller companies (those with fewer than 50 employees) reported difficulty in filling positions. Nearly half of these firms reported that more than 20% of their biotech-related positions had been unfilled for more than three months. This was true for only 1% of firms with more than 50 employees.[21]

GOVERNMENT: GOALS AND ROLE:

Nowhere else is the industry debate more prominent than in the establishment of appropriate government policy and regulations for biotechnology. Most of the industry's regulatory guidance within the U.S. emanates from the government through the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Many of the regulations established as governance for the biotech industry centers around what the government and the general public consider matters of ethics, morality, and safety. The industry tests the limit of our current views on human advancement, and the potential for R&D to generate unintentional consequences that may unleash some form of uncontrollable agent(s) on the general population. Therefore, legislators enact policies that, among others, things try to reduce consumer fears.[22]

Unlike the industrial revolution where new discoveries brought advancements in industrial capacity and improvements in business processes, or the IT revolution that ushered in a new era of computer technology that allowed for faster and more efficient processing of information, hence the Information Age, the biotech revolution is challenging the core knowledge of our existence and the ability to sustain ourselves over longer periods of time. Not only that, it is challenging whether or not we should move beyond reproduction as we know it to creating replicas of ourselves or recreating ourselves in newer and more enhanced forms. Of course, this brings about discussions on the extent to which we will allow various forms of animal (to include human) and plant experimentation. While the latter issue has been a source of debate for hundreds of years, today's biotech research takes the issue to an entirely new level. These and other issues, concerns, attitudes and beliefs, along with the drive, desire, and the basic capacity for human comprehension, give rise to policies and regulations designed to allow for biotech research and development but at a pace that accounts for safety, caution, and limits on every aspect of the business. Both sides, in the biotech regulatory debate, desire to ensure the longevity of human existence.

The USDA, EPA, and FDA individually and collectively (depending on the overlap) encompass and regulate an array of fields within the biotech industry, some with similar goals that drive competition, and some with their own unique set of goals or desired end-states that may result in some new product or discovery that will further advance the field. Federal management and regulatory policies have tried to encircle any potential residual discoveries that might serve as building blocks for further biotech-related R&D and/or product manufacturing for public or specialized consumption. Today, U.S. government regulations apply to biotech in the following areas: agriculture (genetically enhanced crops, etc); intellectual property/patents; funding; morals/ethics; safety; biodefense/bioterrorism/national security; human genome study and implications; cloning (human/animal); embryonic/stem cell research; nanotechnology (although some consider this on the fringes of biotechnology); environment/bioremediation (bio-environmental cleanup, etc.); and medicine (pharmaceuticals/drugs). This list continues to evolve. In March 2005, the FDA issued guidelines intended to encourage pharmaceutical companies to study how genetic variations affects the way people respond to their drugs. These new guidelines are paving the way for yet another field under the umbrella of biotechnology called pharmacogenomics.[23] The terms pharmacogenomics and pharmacogenetics are used interchangeably to describe this science, although the former refers to the general study of all of the many different genes that determine drug behavior, while the latter refers to the study of inherited differences (variation) in drug metabolism and response.[24]

Intellectual Property

Another government role necessary for the health and survival of the U.S. biotechnology industry is protecting intellectual property (IP) through the use of patents, copyrights, and trademarks. Promoting the necessary domestic legal reforms to streamline the application process are critical to improving access to the innovator—whether that is an individual, a commercial entity, or a government agency. The current set of U.S. legal precepts which govern IP must evolve to protect and promote the diverse innovations within the industry. This legal evolution must remain inclusive of the broad spectrum of participants, and must serve as a standard for negotiation and inclusion within the World Trade Organization (WTO) to promote and protect fair trade practices for U.S. commercial interests. While this report addresses biotech IP under two broad geographic spheres—domestic and foreign, both are increasingly intertwined due to the changing views of international commerce, sovereign borders, the role of the WTO, and a host of related friction points.

The rate of ongoing commercial competition, legal change, and innovation throughout the global biotechnology industry is increasing in intensity and becoming more complex. The legal strictures within sovereign regimes and within the international marketplace can not adjust to the speed of innovation brought about by competing commercial interests. In some sense, it is a form of intellectual and economic warfare in which varied commercial and government interests compete for a share of the market place with little to no consideration accorded the small individual innovator. The legal precedents within the U.S., the European Union, Asia, and the WTO lack standardization to enforce and protect intellectual property (IP).[25] In many instances this global competition has become so cutthroat, complex and convoluted that the individual inventor has little chance of filing for or protecting his patents due to legal challenges, rising costs, complexity, copyrights, and trademarks.[26]

Domestic Considerations. The protection of IP through the vast web of U.S. federal regulations (patents, copyrights and trademarks) has been useful in promoting innovation. In broad terms these "rule sets" have been protectionist in nature with a monopolistic flavor aimed at protecting the broad demographics of our society (from the individual inventor to a commercial entity, or a government agency). These regulations have fostered a unique and delicate environment geared towards rewarding risk. "*Never mind that the U.S. patent system stimulates 10 times the significant discoveries of other nations' systems combined, that it is the world's most reliable engine for technological advance and job growth.*"[27] While this system has worked well in the past, the present system holds real challenges. The current methodology of protecting IP involves filing for a patent, trademark or copyright through a 13 step process with the U.S. Patent and Trademark Office (PTO; a sub-agency of the U.S. Department of Commerce).[28] Successful negotiation through the heavy bureaucratic red tape results in a 20 year protection from the time of award. In the realm of bio-development part of this time is consumed in product test and approval, which could take as long as 7-10 years. The end result is to encourage and reward the risks of innovation; but the current rule set fails to account for the long lead time to bring a product to market and the requisite open sharing of technical information (the very openness of the procedure leaves the discovery accessible to competitive forces which may gain competitive advantage through exploiting similar ideas not within the realm of the current patent).[29]

Domestic legislation has also been enacted to further protect intellectual property. The Bayh–Dole Act of 1980 states that its purpose is "*…to use the patent system to promote the utilization of inventions arising from federally funded research or development.*"[30] The Public Health Security and Bioterrorism Preparedness Act of 2002, the Small Business Technology

Reauthorization Act of 2001, and thirteen other bills are further legislative measures to protect and promote domestic IP.[31]

Foreign Considerations. The "extraterritorial reach" of U.S. patent law is limited to the geo-political borders of the U.S.[32] At issue, is how sovereign countries define IP and the application of common rules.[33] The inability to enact common rule sets which recognize IP and to enforce these rules remains problematic. U.S. Biotech firms must take a calculated risk and determine to what extent they will introduce IP within foreign regimes. This very action breeds distrust between peer competitors, within the host country, between regimes, and across the Biotech Industry.[34] Each geographical region presents diverse challenges and further complicates establishing common ground to gain international consensus.

One of the greatest challenges to protecting IP resides within the third world, especially China. The root factors consist of: a poor transition from government to private ownership; no infrastructure for private research and development (to include funding); poor understanding of the exclusivity of patents; a fledgling legal system; government corruption; and extreme competition between new startup firms all desiring to compete in the global economy.[35] Another challenge resides in an unfair competitive advantage accorded privileged firms seeking to exploit gaps and grey areas within the still immature legal system. Lawyers who represent Western companies embroiled in intellectual property disputes in China, however, point to major loopholes in Chinese law and in the country's trademark and patent system as parts of the problem. Many Chinese patents, for example, are granted without examination of their originality, making it easy for local companies to claim others' innovations as their own.[36] Counterfeiting of IP remains one of the most prevalent threats to foreign direct investment in China. "When the joint venture dissolves, or sometimes even while it remains active, the Chinese allegedly make use of the technology or manufacturing processes illegally."[37]

While the challenges remain in China, new hope for improved opportunity within the biotech investment and development community awaits in India. Recent patent reforms within India signal clearly that the WTO's rule sets can have a positive effect. "The new Ordinance, issued by the government for amending the Patents Act, 1970, is likely to affect the farm sector as it extends the product patent regime to agro-chemicals, food and biotechnology products, apart from drugs and pharmaceuticals."[38] Stronger and more precise regulations will level the competitive playing field and serve to encourage increased foreign investment.[39]

Disagreement over patent standards, rights to genetic material, and the effect of biotechnology patents will continue to generate friction in the global market place. The Federal Trade Commissions 2003 report offered 9 recommendations to protect domestic IP, but could just as easily translate or apply these same standards within the WTO. These interests continue to offer a common way ahead and highly useful to garnering consensus within the WTO.[40]

ESSAYS ON MAJOR ISSUES:

Bioethics:

The discussion of ethics in the biotechnology field is growing in importance, in light of new advances in technology, biology, and the publication of sequenced DNA through The Genome Project.[41] The impact on agriculture, pharmacogenetics, nanotechnology, and tissue cloning and cell replacement can barely be assessed due to the unknown realm of possibilities. The challenge is what are the ethical boundaries? Who determines the ethical boundaries—individuals, peer groups, governments, or an ethical board? There may not be one clear answer, but we have an obligation as a society to do so. To understand why ethics is important in biotechnology industry, "…we need to

be aware that it faces challenges unlike those faced in other sectors. Few industries conduct research so likely to become front-page news, or so likely to face intense scrutiny by peers, academics, government and consumers."[42]

Within the biotechnology industry, there are unique technical challenges, which will require an examination of the individual parts: agriculture with genetically modified (GM) crops, gene testing/profiling and the right of privacy, cloning and stem cell research with its applications, and pharmacology. Upon examination of the individual sectors we will have a framework that applies to the sum of all parts of the industry.

GM Foods. At a glance, it seems to make sense that GM crops benefits society as a whole by preserving the environment, increasing the yield and nutritional value of crops that combat famine and malnourishment, not to mention the financial benefits. Nevertheless, GM crops have had a tremendous resistance by the European Union (EU) since the late 1990's.[43] The EU's point of view, however, "…taking genes from one species and putting them into another is seen as 'unnatural' or unethical".[44] However, if we go back to the Hippocratic Oath, "…to do no harm,"[45] presently there are no adverse effects as a result of consuming GM foods. This is an example of the wrongful application of ethics to impose one's bias or to limit the economic well-being of other countries.

Gene Testing/Profiling and the Right of Privacy. Is probably the most controversial area in biotechnology is where the ethical boundaries can be too broad or too narrow with great physiological, social and economical impact. The issue can be broken down into two major issues: gene testing and what to do with the information; and the protection and privacy of access of this information by third parties, which potentially could create employment or insurance discrimination.

There are pros and cons in gene testing and the ethical implications along with it. The pro on gene testing is that such testing has already resulted in dramatically improvements in our lives. Some testing is used for diagnosis and direct physicians appropriate treatments, while others allow families to avoid having children with devastating diseases, or identifying people at high risk for conditions that may be preventable.[46] The cons are gene testing—as well as medical testing in general—suffers from the possibility of laboratory errors. Many in the medical establishment feel that the uncertainties around test interpretations, the current lack of available options for these diseases "…has the potential for provoking anxiety, and the risk for discrimination and social stigmatization could nullify the benefits of testing."[47]

This leads to the issue of discrimination and the right of privacy to one's gene inheritance. Currently there is no federal legislation relating to genetic discrimination in individual insurance coverage or to genetic discrimination in the workplace.[48] Now the only citizens protected in the U.S. are the federal employees by executive order signed on February 8, 2000, by President Clinton.[49] This executive order was endorsed by the American Medical Association, the American College of Medical Genetics, the National Society of Genetic Counselors, and the Genetic Alliance.[50]

Cloning and Stem Cell Research. This ethical issue is the most divisive of all sectors in biotechnology. One of the reasons is the "biopolitics" surrounding this subject in the U.S. Even though there is stem cell research currently underway, the source and application of the research creates great controversy in the U.S., and no clear consensus around the world. An example of this was demonstrated with the selection of "Baby Adam", from among 15 healthy embryos, because he had the right bone marrow to help his sister, who had a rare disease."[51] Such selection would have been illegal in Britain, but not in the U.S. since there was use of public money.[52]

In the area of cloning, the ethical issue not only pertains to human cloning but to animals as well. In November 2004, the ethics committee of the American Society of Reproductive Medicine

said that cloning for fertility treatment "did not meet standards of ethical acceptability".[53] While a poll by Time/CNN found that 67% of people said that animal cloning was a "bad idea,"[54] the ethical debate comes down to a fundamental division on how we see life: viewed through the prism of its intrinsic value vs. its utilitarian value, while cynics say it is a growing war between commerce and culture.[55]

Pharmacogenetics. Pharmacogenetics is the study of how genes influence an individual's response to drugs.[56] This topic necessarily brings up the allocation of scarce resources, fair distribution and burdens and benefits in developing the field of pharmaeconomics, individualized medicine, and individual rights.[57] The first consideration is resource allocation—should research be pursued in this field or allocated for a greater humanitarian need? However, just in the U.S. every year, adverse reaction to drugs possibly kills 100,000 patients.[58] One can argue that the elimination of adverse affects reduces unwarranted cost that consequently will free up resources for other endeavors. The second ethical issue is who benefits from this technology and whom it discriminates against. Because any new technology or procedures are costly, only those who can afford it are the beneficiaries. Policies to remedy this problem may also come at a higher cost for the government in the healthcare sector. Thirdly, individualized medicine may lead the medical community to take shortcuts in diagnosis and treatment. This creates delays in providing adequate treatment with potential harmful consequences. Lastly, because pharmacogenetics addresses predisposition diseases, which patients do we protect? Do we protect the patients who initially received the diagnosis or the sibling and parents that share the same genetic traits? Unfortunately, the lack of privacy protection laws put the family members at risk for discrimination.

Dual Use and National Security. There is no greater fear or danger than the potential dual use of biotechnology and its impact on U.S. national security. The development of biotechnology is intended for the betterment of humanity, but at the same time this technology may fall in the hands of rogue states, transnational terrorist and criminals, or even disenchanted individuals. Because of this threat, there are many challenges for the industry, scientists, and the government. It has an impact on how the industry goes about conducting R&D and marketing to maintain competitive advantage. While for scientists, it affects the culture of open source, peer reviews and the sharing the information across national boundaries in the name of advancing science. The government has the regulatory obligation and constitutional obligation to safeguard its citizens. Too much regulation may restrict competitive advantage of corporations and limit the scientist's ability to do meaningful research. On the other hand, insufficient regulation and oversight may endanger the very citizens that it seeks to protect.

The Science and Technology Workforce:

The U.S. biotechnology industry is heavily dependent on R&D for its continued growth and success. The U.S. has for many years benefited from minimal competition in the global markets for scientists. However, the ready availability of scientific talent from domestic and foreign sources to supply the U.S. biotechnology industry is no longer assured. If labor needs cannot be satisfied by these two sources, U.S. firms may feel compelled to outsource their R&D. Conceivably, either one of these scenarios could effectively reduce U.S. competitiveness in the global biotechnology industry. Along with the rapid growth of the industry, the biotech workforce has also experienced substantial growth over the last 10 years. In fact, this workforce has more than doubled during the last decade from approximately 80,000 employees in 1992 to the current estimate of almost 200,000 employees.[59] This industry growth and subsequent demand for workers is likely to continue—with conservative estimates of 500,000 workers needed by 2012.[60]

With the industry relying so heavily on R&D, satisfying the industry's growing intellectual capital needs presents a tremendous challenge. Eighty-six percent of the biotech workforce possesses an education level well beyond secondary school. In fact, statistics indicate 36% of the workforce has advanced graduate degrees (Ph.D.–19%, M.S.–17%), and the majority of the remaining percentage hold at least a bachelor's degree (B.S.–50%), with the remaining workers being employer trained (14%). Furthermore, due to the highly technical nature of the work, it is difficult for workers from other U.S. industries to transfer into the biotech workforce. Consequently, the biotech industry places a heavy burden on the U.S. education system to provide the necessary scientific expertise—especially in the microbiology, biochemistry, and molecular biology disciplines.

Due to the growth of the industry and its need for highly educated workers—and in particular, in the biological and life sciences—there is increasing pressure on this input market. Unfortunately, the scientific and technical workforce in the U.S. is in a general state of decline, and has been so for a number of years. Because of the industry's growing intellectual capital needs, and the general inability of the U.S. workforce supply pool to satisfy the growing demand for workers, the industry also relies on foreign workers with the necessary scientific skills. There are potential problems however—both economic and security-related—with having significant numbers of foreign workers employed in the industry. The origins and causes for the decline of the U.S scientific workforce, along with the impacts of foreign workers on the biotechnology industry, are explored in more detail below.

Root Causes of the Science and Technology Workforce Problem: There are a number of possible causes for the decline of the scientific and technical workforce in the U.S. The principal reasons include: a long-term decline in the overall federal investment in R&D as a percentage of gross domestic product; a general lack of interest amongst young people in pursuing education in the physical and biological sciences at both the undergraduate and graduate levels; an educational environment where foreign graduate students are earning a significant percentage of the scientific and technical degrees granted by American universities; and long delays involved in recruiting and training a highly-educated workforce with the required skills needed to replace the scientists of the current baby-boom generation who are just now retiring.[61]

With regards to reallocation of the labor market from other industrial sectors, the education requirements seem to preclude easy transfer of this labor into the biotech sector. There also appears to be unwillingness in the workforce to commit to the additional years of technical training—even when supplied by the employer—to facilitate the transition.

Role of Foreign Workers in the U.S. Biotechnology Industry. Under current U.S. immigration law, foreign workers with unique skill sets that are not available in the existing domestic labor pool may obtain permission to stay and work in the U.S. for up to six years. These workers are designated as H-1B visa holders; current federal law caps the number of H-1B visas at 65,000 per year. The annual limit for this controversial "guest worker" program has already been met for fiscal year 2005—U.S. Citizenship and Immigration Services, which processes the applications for the H-1B program, is no longer accepting petitions for visas for initial employment for this fiscal year.[62]

Biotechnology companies have frequently used workers with H-1B visas, since their skills frequently matched the most pressing employment needs of the industry—such workers are considered critical to industry success and competitiveness. Skilled foreign workers are typically paid salaries comparable to American workers in the same jobs. Estimates indicate that between 7%-10% of the biotech workforce hold H-1B visas; this percentage increases if bioinformatics is included.[63] However, foreign workers only provide a temporary solution to shortages in the domestic labor force—shortages that point out the inadequate production of appropriately trained U.S. citizens.

Implications for the U.S. Biotechnology Industry. While a large proportion of the H-1B workers remain in the U.S. for the entire six years, that trend may not continue in the future. As increasing numbers of international biotechnology firms develop and mature outside of the U.S., increasing numbers of these foreign nationals may feel compelled to return to their countries of origin to work in their native biotech industries. In addition, other countries may recruit them to work in their biotech industry. If industry labor needs cannot be satisfied by either domestic or foreign worker sources, U.S. firms may feel compelled to outsource their R&D in order to remain competitive.

Conceivably, any one of these scenarios could reduce U.S. competitiveness in the global biotechnology industry. Furthermore, since so much of the industry is knowledge-based, any reduction in the workforce—U.S. or foreign—would mean not only the loss of workers, but also the loss of intellectual property, since this knowledge is worker-transportable. This scenario is especially problematic on the foreign worker side, since many countries do not necessarily adhere to international patent and trademark laws.

There is also a potential security issue associated with foreign nationals in the biotech industry. Considering the list of countries that supply H-1B visa holders—such as India, China, Pakistan, et al., one cannot easily dismiss the notion that some of the foreign nationals who to return to these countries may be compelled by their governments to use their knowledge and skills for more sinister purposes. This is a concern not only for the biotech industry, but also for U.S. national security policymakers.

Nanobiotechnology:

The biotechnology industry is clearly a research-driven enterprise that solves "macro" problems with "micro" sciences—and more recently—with "nano" sciences. The nexus between biotechnology and nanoscale science and technology, commonly referred to as "nanoscience" or "nanotechnology," has grown significantly. In fact, the term "nanobiotechnology" was coined to describe the merger of these two disciplines. This integration of nanotechnology with biotechnology—as well as with information technology is expected to further accelerate over the next decade. While many definitions for nanotechnology exist, the National Nanotechnology Initiative (NNI) has defined it in three parts: research and technology development at the atomic, molecular, or macromolecular levels, at the length scale of approximately 1-100 nanometers (1-100 x 10^{-9} meters or 1-100 nm) range; creation and utilization of structures, devices, and systems that have novel properties and functions because of their small size; and the ability to control or manipulate on the atomic scale.[64] An additional caveat imposed by the NNI definition is all three of these guidelines must be present for the technology to qualify as nanotechnology.

Nanobiotechnology, on the other hand, has been defined as, "…a field that applies nanoscale principles and techniques to understand and transform biosystems (living or nonliving), or uses biological principles and materials to create new devices and systems integrated from the nanoscale."[65] Since many of the basic life processes occur at the sub-cellular level—i.e., the nanoscale—understanding the fundamental structure and design of these biological systems has the potential to significantly influence medicine and the life sciences. Development of this fundamental understanding at the nanoscale holds great promise for the synthesis and fabrication of devices for measuring the characteristics of these cells and sub-cellular components—which some biologists now refer to as "functional nanosystems."[66]

Applications of Nanotechnology to the Field of Biotechnology: The increasing scientific interest in the intersection of these two fields is based on the idea that nanotechnology offers biology new tools, and that biology offers nanotechnology access to new types of functional nanosystems—i.e., components of the cell.[67] The merger of these two disciplines to create the field of

nanobiotechnology reflects the increasing importance of nanoscience in the creation of novel types of biomaterials. These new materials could be used in such things as: tissue engineering and cell patterning, sensors that rely on conformational changes in macromolecules for use in diagnostics, "nanopores" that allow the passage of single molecules for sequencing deoxyribonucleic acid (DNA), nanomaterials for use in imaging single molecules or cells, and new materials or devices for use in drug delivery or as therapeutics.[68]

For example, researchers are currently exploring how DNA can be used for non-biological applications, such as the building of structures and devices whose essential elements and mechanisms range from 1-100 nanometers—i.e., the nanoscale. Because of the inherent size of DNA (e.g., the width of the DNA helix is approximately two nanometers and it twists a full revolution every 3.5 nanometers), it is considered a versatile framework for making these devices and structures. Depending on its sequence of base pairs, DNA has highly specific interactions with other chemicals. Biologists have exploited the use of these "sticky ends" in genetic engineering for years.[69]

Because of this feature, DNA is considered an ideal molecule for building nanoscale structures, since strands of DNA can be "programmed" to assemble into complex arrangements simply by producing the strands with the appropriate combinations of sticky ends. Novel uses of this technique include DNA "scaffolds" that hold "guest molecules" in orderly arrays for crystallography, or used to build materials with precise molecular configurations. X-ray crystallography—used to determine molecular structure, is an important step in the design process of new drugs. In addition, new materials could be constructed—either made by the DNA or made of it—with exacting molecular precision. DNA machines with actual moving parts could be employed as nanomechanical sensors, switches, and tweezers.[70]

Changes in Physical Properties at the Nanoscale—Why the Familiar Rules Don't Apply: Major changes in the physical properties of ordinary materials occur when it is reduced to the molecular dimension. For example, nanomaterials have vastly increased surface area—often by a factor of million(s). This fact alone makes these materials considerably more reactive—they are quicker to ignite, melt, and absorb. These unique properties also lead to new concepts such as more efficient drug dosages—delivered in quantities of "nanospecks," or highly responsive sensors which can detect individual molecules. New generations of prosthetic and medical implants whose surfaces are "molecularly designed" to interact with the body could be developed, along with the ability to attract and assemble the raw materials in body fluids that can regenerate bone, skin, or other missing or damaged tissues.[71]

Nanotechnology Question Marks: The public's general misunderstanding of nanotechnology—fueled by imaginative science fiction, has distorted the truth about the technology. Such inaccurate portrayals not only threaten public confidence in the integrity of the science, but could also precipitate a global backlash amongst activists, similar to the reaction against genetically modified food. Already, such groups as the "Friends of the Earth" have warned of the dangers of nanotechnology, even calling for a global moratorium on the production of all nanomaterials.[72]

A more legitimate challenge for the nanobiotechnology industry is to ensure that these nanomaterials are safe for the human body and the environment. Worries grew in the spring of 2004 when researchers at Southern Methodist University reported brain damage in a large-mouth bass that had been swimming in an aquarium stoked with these carbon-based nanoparticles known as buckyballs. Although far from conclusive findings, such findings raised scientific concern worldwide.[73]

In response to these as well as other safety concerns, the Environmental Protection Agency has started an assessment of the effects of nanoparticles on biological systems to ascertain whether they do indeed present unique health and environmental risks. At the same time, the U.S. National

Institute of Standards and Technology is developing new means of measuring nanotechnology product dimensions, behaviors, and properties, in order to establish standards for quality assurance and control of future nanotechnology products.[74]

The Pharmaceutical Industry:

The U.S. pharmaceutical industry occupies a critical sector of biotechnology. Using genetic engineering techniques, biomedicine can produce an increasing number of drugs and diagnostics derived from human genes. This is known as biologics—these medicines are generated from biofermentation techniques that use microbial or animal cell cultures.[75] The biotech and pharmaceutical drug products are frequently referred to as "biotechnology medicines." For instance, according to the Boston Business Journal, "*…the Tufts Center for the Study of Drug Development says that advances in biotechnology research and development will result in nearly 50 new biotechnology medicines gaining marketing approval from the U.S. Food and Drug Administration (FDA). That's out of about 250 protein-based biotechnology therapeutic products in development worldwide*."[76]

Drug prices are difficult to rationalize without a full understanding of what is included in the cost. Prices in other countries generally reflect the low incomes and the highly politicized nature of most foreign health care systems that rely on price controls and access restrictions. For example, drug prices are low in Mexico compared to those in the EU and the U.S. because Mexico has a much lower per-capita income and spends far less on health care and pharmaceuticals. The Mexican government also regulates drug prices and provides only limited patent protection for pharmaceuticals.[77] On the surface, Canada appears to have lower drug prices but the reasons for this are the slow growth of the Canadian economy and the recent decline of their dollar. As a result, many goods, not just prescription medicines, are cheaper than in the U.S. Moreover, Canadians have the advantage of having fewer and less costly product liability lawsuits and litigation than the U.S in this market.[78]

Health care cost is undeniably increasingly expensive, but the alterative of not treating illnesses and not having access to critical medications are even more costly. In fact, new pharmaceuticals are responsible for almost half of the reduced disease mortality between 1970 and 1991. Furthermore, some health care professionals believe that every new drug approved during that time saved over 11,000 life-years annually. In addition, today's physicians/doctors have at their disposal medications and technologies that provide for the immediate diagnosis and treatment of most of the disorders that affect modern man. Hundreds of new medicines are in development for cancer, heart disease, strokes, Alzheimer's, infectious diseases, and AIDS. A couple of decades ago treatment for AIDS was non-existent; by 1987, there was one drug, AZT. Now, there are at least 74 anti-AIDS drugs available and still more under development.[79]

The incentives for the Pharmaceutical companies to take high risks in investing capital for high cost pharmaceutical R&D are primarily the IP protection of exclusive patent rights. These rights protect them and promise potential rewards and high profits to cover their investment costs of R&D and provide returns on their capital for future R&D efforts. From "*…the time research begins to develop a new prescription medicine until it receives approval from the Food and Drug Administration (FDA) to market the drug in the United States, a drug company typically spends approximately $802 million over the course of 10 to 15 years*."[80] Even such substantial investments by pharmaceutical firms do not guarantee results and return on investments. "*Of every 5,000 to 10,000 substances reviewed by FDA, only about 250 make it to the animal-testing stage. Around 5 of them go on to human clinical trials. Only one, on average, makes it into the market. Even at that*

point, only 3 out of 10 new drugs actually make money. Those few must pay for everything—research, administration, regulatory delays, and failures."[81]

Steady increases in the demand for new drugs that result in higher prices and heath care costs reflect America's desires for improved medications, health and longer life. The highest-priced drugs do not represent luxury goods but address serious and painful health conditions. About half (50.6%) of the $22.5 billion increase of the prescription drug spending in 2001 occurred among just nine categories of medicines—those used to treat depression, high cholesterol, diabetes, arthritis, high blood pressure, pain, allergies, ulcers, and other gastrointestinal ailments.[82] The increase in demand is also a product of today's lifestyle—fast food, two income families and the aging baby boom generation. To feed this growing demand, we need to ensure continued innovation and breakthrough development of new drugs are encouraged and incentivize companies to invest in R&D. Furthermore, there is a critical need for the continuous increase in medical innovation and government policy/support to encourage and foster the collaboration and joint R&D ventures between biotech and pharmaceutical firms and other research institutions to develop and produce biotechnology medicines to prevent, cure sickness and improve wellness. Any government intervention or legislative initiatives to reduce prices would definitely take away companies' incentive to invest in new drug development, limiting production of and access to new, life-saving compounds.[83]

Agriculture and Genetically Modified Foods:

The U.S. is by far the world's leader in the bio-agriculture industry with more than half the world's total genetically modified (GM) crop production in 117.6 million acres.[84] According to the U.S. Department of Agriculture, this is an 11% increase over 2003 which is due primarily to increased planting of GM corn and soybeans. Ninety percent of the world's GM crops are dominated by four countries: United States (59%), Argentina (20%), Canada (6%), and Brazil (6%). There was an increase in global GM crop acreage of 20%, 32.9 million acres between 2003 and 2004.[85] The predominant GM crops are herbicide-tolerant (HT) and insect-resistant (Bt) soybeans, corn, cotton, and canola. In 2004, HT crops dominated U.S. biotech crop acreage. Specifically, HT soybeans reached 85% of U.S. total soybean acreage; HT cotton reached 60% and HT corn reached 18% of their respective total crop acreages.[86] In 2004, the share of total U.S. corn acreage for Bt corn increased from 29% to 32% largely due to the introduction of a new Bt corn variety that is resistant to the corn rootworm, a pest that may be more destructive to yield than the European corn borer.[87] Several companies are working on the next generation of GMOs which will benefit consumers directly and will involve improvements in food quality, safety, and nutrition.[88] It is expected that oil crops with enhanced levels of healthy oils like omega-3 will reach the market in the next five to seven years.[89] Other examples of GM foods with increased health and nutritional value that are in development include golden rice and canola oil with high vitamin A and potatoes with a 30% increase in protein content.

In recent years, GM foods have stirred a debate among politicians, activist groups, and consumers, particularly in Europe, concerning the benefits and risks of GM foods, with more focus on the risk side of the equation. The EU's concerns have impacted U.S. ability to market and export GM foods to the EU**.** Since May 2003, the U.S. and EU have been in WTO litigation over the EU's 1999 suspension of consideration and approval of GM products for planting and import. EU consumers fear GM foods as a result of their experience with the "mad cow" crisis, creating a lack of confidence in the government and regulatory system to protect the food supply. The EU incorporates the precautionary principle in its Regulation on General Food Law to ensure that precaution is used within the overall framework of risk analysis. Precaution is relevant when there

is a circumstance in which science lacks the ability to ensure that there will not be harmful health effects. But, precautionary measures shall be applied only as necessary for health protection while restricting trade as little as possible.[90] Opponents of the precautionary principle, including the U.S., argue that its application to GM foods is problematic. Using the precautionary principle establishes a regulatory framework based on verifying that a new product or technology causes no harm. This essentially means that perhaps the farmer, the regulating agency, or maybe even the biotechnology company must prove a negative, a logical impossibility.[91]

During the moratorium, the EU established regulations for the labeling of GM foods. The EU believed that more extensive labeling information would help restore consumer confidence in the food regulatory system, providing consumers greater choice about what they eat and build confidence in GM products.[92] The Traceability and Labeling Regulation requires that biotech products be traced throughout the commercial chain, and that food containing biotech products comply with certain labeling requirements. The Genetically Modified Food and Feed Regulation provides new approval procedures for biotech food and feed products.[93] U.S. government officials, farm groups, and biotechnology companies regard the rules as costly, unworkable, unenforceable, unnecessary and discriminatory against U.S. agriculture products.[94] Since the U.S. commodity grain system routinely mixes in GM varieties with conventional varieties, producers and farmers will have to segregate crops and foods derived from GM crops at every step of the harvesting and food production processes. Further, labels that identify foods as derived from biotechnology are likely to be seen by consumers as "warning labels" which would decrease the demand for the products.[95] The U.S. prefers and uses a voluntary labeling policy. The labeling debate indicates the need for internationally agreed to standards for GM products being traded globally because there are different approaches being used around the world. The United Nations international food standards body, Codex Committee on Food Labeling, has been unable to reach consensus on GM food labeling. They will address it again at their meeting in Malaysia in May 2005.[96]

Although the WTO dispute has not been settled, the EU has recently taken steps to open up trade and acceptance of GM foods. The EU's moratorium was lifted by default when the European Commission approved two new crops, Syngenta's Bt11 sweetcorn for human consumption and Monsanto's NK603 maize, in May and October 2004, respectively.[97] However, public opposition to GM foods remains strong in the EU. A recent survey by the European Commission found that 70.9% of European shoppers were hostile to foods containing GM ingredients.[98] In addition, farming groups, regional bodies and local politicians have established GM-free zones, raising the question as to whether there can be coexistence; that is, the regulation of GM crops so that they do not cross pollinate and contaminate conventional agriculture. The EU commissioner has requested a report by the end of 2005 on how different countries have approached coexistence to determine if the EU framework can learn any lessons for adoption.[99]

There is divided state opinion within the EU regarding the role that GM products can play in European society. Therefore, the Commission has called for a study on the cumulative long-term effects of GM crops on human and animal health. The objectives of the project include: assessing and documenting the adequacy of existing risk assessment methodologies and protocols for judging the impact of GM crops; and to identify any possible gaps in knowledge.[100]

Biological Warfare:

The threat of bioterrorism is no longer limited to just the potential for state sponsored attacks. The primary threat is likely to come from terrorists, non-state actors, and individual operators who may have gained access to dangerous pathogens. The threat posed by dangerous pathogens also appears to be changing. Bioweapons could become increasingly diverse and potent

as a result of discoveries in the life sciences (e.g., medicine, and agriculture).[101] A panel convened by the National Academy of Sciences noted that the genomic revolution could produce biologically engineered agents, or unconventional pathogens that could be combined with known pathogens to produce virulent "designer" BW agents.[102] We also need to be concerned about the remnants of the Soviet offensive biological weapons program that produced strains of antibiotic resistant anthrax and hemorrhagic fever viruses (e.g., Marburg). [103] The Soviets are known to have tested and weaponized these novel agents.[104]

In April 2004, President George W. Bush issued a Presidential Directive (PD) "Biodefense for the 21st Century" aimed at addressing the unique, growing threat presented by the application of biotechnology to weapons development. The PD breaks biodefense into four pillars: threat awareness, prevention and protection, surveillance and detection, and response and recovery. Broadly, these four pillars span intelligence-based, pro-active posturing; multi-dimensional, multi-national diplomatic prevention; defense via surveillance and detection; and a national response plan based in pharmaceutical protection and post-exposure treatments.

Biodefense. Following the October 2001 anthrax letter attacks, the U.S. government realized there was no market for the products that it now needed. As a result, President Bush announced "Project Bioshield" in his January 2003 State of the Union address. Project Bioshield is a comprehensive effort to develop modern, effective drugs and vaccines to protect against biological as well as other weapons.[105] In July 2004, President Bush signed Project Bioshield into law. Bioshield authorizes and appropriates up to $5.593 billion over 10 years (through 2013) for the purchase of vaccines, drugs, and diagnostic tools for the Strategic National Stockpile (SNS).[106] The primary component of SNS is development and purchase of vaccines for anthrax, smallpox, and plague.

To date, only a small amount of Bioshield money is obligated. Major U.S. biotechnology firms appear content to remain on the sidelines. A survey of 30 expert leaders from academia, government, and industry (17 from the pharmaceutical and biotech industries), concludes that Bioshield, is necessary, but not sufficient to entice industry leaders to enter the biodefense industry.[107] There are essentially four reasons for this, including; no product turnover or opportunity to replenish the stocks; lack of sufficient intellectual property protections; insufficient indemnification protection; and, no guaranteed government funding for development of experimental biodefense vaccines and drugs. Senators Lieberman and Hatch recognized the deficiencies of Bioshield; on March 19, 2003, they proposed "Bioshield II." [108] The purpose of Bioshield II is to provide additional incentives for biotechnology companies to enter the biodefense market. A major incentive currently contained in Bioshield II is to provide increased liability protection. Currently, Bioshield II is in draft legislation before the Senate.

Military Vaccines. Health experts believe that immunization is the most effective means of preventing infectious diseases.[109] Vaccines have two significant advantages for military readiness—the first is that preventative vaccination reduces readiness-associated impact on troop strength through death or illness vice reliance on post-event treatment. Secondly, "*…vaccines are the most cost effective way to protect service members from potential disease*".[110] The U.S. military's vaccine problems, however, are symptomatic of the larger vaccine issues confronting public health, homeland defense and military vaccine requirements (e.g., time, and intellectual property).

DoD vaccine R&D priorities are: vaccines for threat agents for which a vaccine currently doesn't exist (e.g., avian flu, Marburg, Ebola); vaccines that need improvement and are slow to achieve immunological response or requiring multiple shots; and development of multi-valent vaccines.[111] As we move forward, military vaccine requirements are likely to change from multi-valent to multi-pathogenic vaccines in order to develop immune response to the broad array of infectious disease threats. The technologies for these vaccines will require a greater understanding

of the immune system and bio-informatics in order to drive to a greater immune response while identifying the best antigenic targets; advances in vaccine production and delivery methods will further enhance this invisible weapon system's utility.[112]

Surveillance and Detection. Surveillance and detection focuses on attack warnings. A requirement for an effective defensive network is one that can detect agents, assess the associated threat and mobilize the appropriate resources to counter it. The speed at which the detection, identification, and defensive actions occur will likely limit the scope of the damage and lessen the impact of the bioattack. The combined initiatives of BioWatch,[113] and BioSurveillance,[114] among others, provide fundamental building blocks for ensuring a national surveillance and detection program.

Syndromic surveillance is the ongoing, systemic collection, analysis, interpretation, and application of real-time indicators for detecting disease outbreaks *before* public health authorities discover it.[115] It applies automated data analysis tools to screen generic clinical illness symptoms (e.g., fever, rash, and respiratory complaints) to detect unexpected patterns, or illness clusters, that warrant investigation.[116] It is based on the theory that screening for certain symptoms can provide public health officials with the earliest evidence of a bioterror attack *before diagnoses* are confirmed and reported to public health agencies.[117] Syndromic surveillance can buy critical time to *mobilize* the public health system[118]

Unconventional Applications of Biotechnology:

Unconventional applications of biotechnology include pharmaceuticals, marine biotechnology, genetic engineering, bio-energetics, biomimetics, biomaterials, and environmental biotechnology. Examples include:

Pharmaceuticals. *Cocaine Vaccine*: An immunotherapeutic approach to treating cocaine dependence in the form of a vaccine has recently been developed. The vaccine induces the patient's immune system to produce antibodies that bind the cocaine molecules to antibodies upon entering the bloodstream thereby preventing cocaine from crossing the blood-brain barrier to act on receptor sites in the brain. The impact of this promising application is that it can be an effective treatment for million of cocaine addicts who wish to end their dependence on the drug.

Marine Biotechnology. *Treatment of Mucociliary Disease*: Researchers working with red tide toxin at the University of North Carolina's Wilmington's Center for Marine Science have discovered two new compounds that improve the flow of mucus through the respiratory tract, allowing airways to clear more quickly and efficiently for victims of cystic fibrosis and similar lung diseases.[119] Impacts of this application is that the doses required to gain beneficial effects are much lower using this technology than the current treatment resulting in greatly reduced negative side effects.

Genetic Engineering. *Mammal Parthenogenesis*: Scientists have produced a mouse through parthenogenesis, a process whereby the genetic exchange between sperm and egg is circumvented and the egg becomes the sole source of genetic material in creating a new embryo. Until now, it had been considered biologically impossible for two mammals of the same sex to combine their genomes and produce viable offspring. This research will impact areas of study such as embryology, assisted reproduction, and even cloning. In the future it may even allow two women to have a biological child without the participation of a male.[120]

Bio-Energetics. *Microbial fuel cell*: Environmental engineers at Penn State University have generated electricity from a microbial fuel cell without adding any other bacteria. The naturally occurring bacteria in wastewater drive power production via a reaction that allows them to transport electrons from the cell surface to an anode. Through this application microbial fuel cells would

make the process of purifying wastewater much more economical for companies operating sewage treatment plants and provide access to sanitation technologies to developing countries throughout the world. [121]

Biomimetics. *Self Cleaning Materials—The Lotus Effect:* A group of German scientists have developed materials that mimic the surface of the lotus plant. These materials have a self-cleaning surface that resist adherence by any other material. Possible applications include paints, roof tiles, textiles and material coatings. One interesting application is aircraft skin paint.

Biomaterials. *Spider's Silk from Goat's Milk*: Nexia Biotechnologies has developed a method to introduce silk-producing genes called fibroins into New Zealand miniature goats.[122] Given the difficulty with harvesting spider's silk from spiders, these genetically enhanced goats can produce up to 15 grams of spider silk per liter of milk, significantly more than what a spider could make. With these increased quantities, commercial applications such as brake pads, surgical sutures, lightweight bulletproof vests and clothing, and even arresting cables for aircraft become cost effective.

Environmental Biotechnology. *Phytoremediation*: Phytoremediation is a type of bioremediation that uses genetically modified plants and trees to clean up contaminated sites. Contaminants such as mercury and arsenic are absorbed by the plants and either metabolized into a less harmful substance or stored in the leaf and root system. By harvesting the latter, contaminants can be more safely disposed of or collected for further processing or recycling. The impact of this technology is that it could prevent or minimize site contamination before it even begins thereby reducing stress on the environment. *Biofilm Protection:* Biofilms are bacterial slime layer which naturally develop on any submerged structure. They form on almost any material including stone, metal or wood. They constitute a major problem for any industry that deals with flowing water systems. Scientists are developing paints and other coatings made with biological ingredients to control biofilm formation on submerged surfaces. These coatings blend metabolically active bacteria (living paints) or enzymes into coatings.[123] These bacterial coatings produce enzymes that enable it to feed on the biofilm. Since they contain live bacterial organisms, these coatings can regenerate indefinitely. Another innovative application is to use the bacteria in developing a non-toxic "biocement" material which can be used to build structures that inhibit biofilm formation. This application of biotechnology can greatly benefit water treatment plants, the oil industry, the military, and even the recreational boater.

BIOTECHNOLOGY IN ASIA: CHINA, HONG KONG, AND SINGAPORE:

China. China has been aggressively investing in biotech since 1999. The seeds for this added investment and focus were made in the 1996-1998 863 Programs. The 15th and 16th People's National Congress generated numerous science and technology initiatives—specifically in biotech—to establish Chinese institutional and intellectual capacity. Their goal was and is to compete regionally and then globally, specifically with the U.S., for eventual dominance in the biotech market. The government decided to invest in biotech as a priority since the U.S. government was so heavily invested in information and software technologies.[124] The Chinese biotech market earned $3 billion in 2003 and is projected to earn $9 billion by 2010.[125] China and India are now leading the Asia-Pacific biotech industrial effort which outperformed Europe by 40% in 2003 according to the United Nation's Industrial Development Organization.[126] China's main sources of biotech growth will be in bio-agriculture, genomic sequencing, biochips, traditional Chinese medicines, bioinformatics, stem cell research, and bio-manufacturing.[127]

Chinese investment strategies reflect the continued growth and importance of biotech as a staple in China's quest for high-tech competitiveness. China invested $180 million in biotech

between 1996-2000, but dramatically increased that rate by 400% from $100 million annually in 2001 to $1.2 billion by 2005.[128] Their current 5-year plan projects an annual investment rate of $8.8 billion by 2010.[129] In aggregate, they have approximately 500 biotech firms, of which 39 are publicly traded.[130] The U.S., in comparison, has 1,466 biotech companies of which 318 are publicly traded.[131] China has approximately 300 publicly funded laboratories and 50 start-up companies with over 20,000 researchers in life sciences—located mainly around Beijing, Shanghai, and Shenzhen.[132] China's current annual biotech investment is small compared to the U.S.'s $15.7 billion**.** The U.S. also employs over 200,000 people in biotech as compared to China's 50,000.[133]

China can also leverage several competitive advantages in the global biotech market. First, the protracted drug research and developmental process is very expensive.[134] China is well positioned to benefit from the pre-clinical, non-human testing of drugs because their testing and research costs are less than one-fifth U.S. costs.[135] Second, China has significantly lower scientific labor costs—the annual salary for a U.S. Ph.D. researcher is $85,000 as compared to China's $25,000. This is one of the primary reasons large pharmaceuticals like Novartis and Pfizer established research facilities in China.[136] Third, China currently lacks many of the ethical constraints restricting controversial genetic research and experimentation.

However, China has a number of challenges that must be overcome before it can obtain its current goals of regional dominance and global competitiveness. The number one impediment is the lack of adequate intellectual property (IP) rights, and more importantly, enforcement mechanisms. Second, and a related factor, is their poor record to adopt World Trade Organization (WTO) standards. Third, in part due to the first two factors, China does not have the foreign direct investment (FDI) and private investment growth needed to incentivize its biotech industry. Lastly, China is a centralized communist society with rampant corruption at the federal and provincial levels down.[137] The Chinese need to remedy these problems to attain their goals of further economic liberalization, gains in domestically-generated high-tech products, and prioritized self-sufficiency.

Hong Kong. At the stroke of midnight on July 1, 1997, Hong Kong's rule was returned to the People's Republic of China (PRC), ending 156 years of British Rule.[138] Hong Kong's aggressive, western-oriented community realized the potential effects of these changes in 1988, began the development of modern high-tech R&D facilities with a focus on information technology and biomedical sciences which rivaled those of its competitors in Shanghai and Singapore. This situation literally placed Hong Kong in a biotechnological "catch-up" mode which still continues today. As a British colony, Hong Kong was not available to receive earlier investments from the PRC in high-tech R&D facilities such as The Shanghai Zhangjiang Hi-Tech Park established in July of 1992.[139] However, Hong Kong's biggest asset—its human capital—has made a Herculean effort, through investments and intelligent process management, to meet and manage the challenge of bringing its biotech community to world-class status. Today, after receiving many groundbreaking biotechnology patents for discoveries ranging from skin care gels, to pig growth hormones, Hong Kong and its resident companies are beginning to reap the benefits of its efforts, as the city has achieved an acknowledged status as a world leader in several advanced biotech areas such as genomic research and human vaccine development.

Hong Kong has developed a well-known and well-earned position as the "Gateway to China." Its traditional economic pillars, banking, finance, service and manufacturing industries had been engrained in the culture of the city and consequently, there was very little focus on the biotech industry. With China's entry into the World Trade Organization, and the change to Chinese rule, Hong Kong's traditional role was no longer needed, as Chinese mainland companies could be directly contacted by western organizations. However, the combined leadership of Hong Kong and the PRC provides access to many of the elements which has allowed Hong Kong to quickly

restructure itself, and pursue leadership in information technology and biotechnological research and development via: access to astounding levels of capital; an aggressive, profit-oriented intellectual base of government and private leaders; a system of laws (the Basic Law of Hong Kong) which will prevail for the next 50 years by agreement with the British government and the PRC, maintaining the rights to property ownership and personal freedoms, and; access to western specialists in all areas of technology, and finance and academia.

Hong Kong's aggressive approach towards the development and funding of its biotechnological research industry has already begun to bear fruit. While the process of producing vaccines and drugs for human use is expensive and extended, Hong Kong's understanding of the outsourcing approach to R&D has placed it in a strategic position in the biotech industry.

Singapore. Singapore, a small city-state in S.E. Asia, has virtually no natural resources. Its future growth depends heavily on domestic human capital to maintain technological advantage over its neighbors. Singapore lost some of its early lead in computer technology that offered cheaper labor for manufacturing and assembly.[140] To slow the loss of manufacturing jobs, Singapore plans to make biomedicine the fourth pillar of its economy alongside electronics, chemicals, and precision engineering. The Singapore government believes that because of the complexity of the industry, the infrastructure for biotechnology cannot easily be transplanted to a cheaper offshore location.

In 1999 the Singapore Economic Development Board (EDB) canvassed the leading multinational pharmaceutical and biotech companies and asked them what it would take for them to invest in Singapore. The companies wanted tough patent protection; lengthy and considerable tax breaks, and government investment.[141] The EDB worked to address these issues in order to lure multi-national companies to Singapore. The early results are impressive—the biomedical sciences industry has doubled in size since 2001.[142] Singapore's growth is forecasted at 9%, second only to China in Asia. In 2004 Singapore's Biomedical Sciences (BMS) industry grew to S$15.8 billion, a 33.2% increase over 2003 and surpassing the goal of S$12 billion.[143] Much of this growth is attributed to manufacturing exports and in particular, pharmaceuticals. However, expectations for 2005 are not as good, with pharmaceutical output likely to be flat due to pressure from generic firms.[144] The combination of intellectual property laws, corporate tax breaks, and an educated workforce has driven this growth.

Singapore's overall economic goal is to develop the life sciences industry to the point where it can achieve the same level of success as the other three major economic sectors: electronics, chemicals, and engineering.[145] Leading the initiative is the EDB and Singapore's Agency for Science, Technology, and Research (A*STAR) under the Ministry for Trade and Industry. A*STAR is a government agency in charge of overall coordination of Singapore's Biotechnology initiatives. The long-term plan is to move Singapore from manufacturing drugs to inventing and testing them.

CONCLUSIONS:

The great potential for biotech breakthroughs is close enough and/or seemingly real enough for vast programs with billion dollar budgets to be put in place. Regulatory, structural and labor issues still exist in many locales that serve to impede the entrepreneurial and technology transfer efforts so crucial to bringing scientific research into the commercial marketplace. The world is still in the early days of the biotechnology revolution. The increasing size of biotech companies, the breadth and depth of current research efforts, and the tremendous advances made in the field of genomics serve to motivate countries around the globe as they rush to jump on to this fast moving train.[146] The U.S. has a significant competitive advantage in biotechnology primarily due to its economic power and efficiency, coupled with its massive science & technology capability.

The seemingly unchecked and rapidly rising cost of healthcare is likely to cause a change to U.S. government policy regarding the drug industry. A likely goal might be to reduce the percentage of the cost for drug research and development paid by the U.S. consumer. Unless changes to the IP regulations are instituted, it's likely to have a large negative impact on the profitability of products within the biotech sector. Promoting the necessary domestic legal reforms to streamline the patent application process are critical—this legal evolution must remain inclusive of the broad spectrum of participants, and must serve as a standard for negotiation and inclusion within the World Trade Organization to promote and protect fair trade practices for U.S. commercial interests. Any change that erodes the potential profits of the biotechnology industry will require careful consideration, as the likelihood of damaging the sector's ability to gain access to necessary capital is large. The current market system and the access to capital it provides are instrumental to the U.S. ability to maintain a competitive global advantage in biotechnology.

As U.S. labor rates continue to outpace the world, the U.S. science and technology workforce contracts, and the foreign science and technology workforce expands, more biotech firms will rely on outsourcing to satisfy their research and development needs. This appears to be a significant negative trend for continued U.S. competitive advantage. Because of the investment in time required to change this trend, the U.S. government must work with industry to quickly address this problem through more investment and targeted education tax credits.

The U.S. continues to lead the world in biotechnology, but the rest of the world is working hard to catch up. Over-regulation and a declining technical workforce require immediate attention by U.S. policymakers. This sector is too important to the health of the national economy for the U.S. to not maintain its competitive advantage in biotechnology.

ENDNOTES

[1] U.S. Congress, Office of Technology Assessment, "Biotechnology in a Global Economy," OTA-BA-494, U.S. Government Printing Office, Washington, D.C., October 1991, <http://www.wws.princeton.edu/~ota/ns20/year_f.html> (accessed 12 March 2005).
[2] UniGuide, Academic Guide to the Internet, <http://www.aldea.com/guides/ag/biotx.html> (accessed 12 March 2005).
[3] Biotechnology Industry Organization, "Biotechnology Industry Facts," June 2004, <http://www.bio.org/speeches/pubs/er/statistics.asp> (accessed 12 March 2005).
[4] Ibid.
[5] Ibid.
[6] Standard & Poor's Industry Surveys, *Biotechnology*, 23 December 2004, New York, NY.
[7] "Biotechnology Industry Facts."
[8] Standard & Poor's Industry Surveys.
[9] U.S. Department of Commerce, "A Survey of the use of Biotechnology in U.S. Industry," (October 2003).
[10] "A Survey of the use of Biotechnology in U.S. Industry."
[11] "Biotechnology Industry Facts."
[12] Ibid.
[13] "A Survey of the use of Biotechnology in U.S. Industry."
[14] "Biotechnology Industry Facts."
[15] Ibid.
[16] Alamy, "An overdose of bad news", *The Economist*, 17 March 2005.
[17] "A Survey of the use of Biotechnology in U.S. Industry."
[18] Alamy.
[19] "A Survey of the use of Biotechnology in U.S. Industry."
[20] "Biotechnology Industry Facts."
[21] "A Survey of the use of Biotechnology in U.S. Industry."
[22] Shelton, Jeffery, "Emerging Biotech Regulatory Policy," The Industrial College of the Armed Forces Student Paper, Fort McNair, Washington DC, AY 2004-2005, 1. [Note: submitted as a spring semester economics paper, 21 March 2005.]
[23] Pollack, Andrew, "F.D.A. Issues a Guide to Gathering Genetic Data," *The New York Times*, (23 March 2005): 1, <http://www.nytimes.com/2005/03/23/business/23pharma.html?adxnnl=1&adxnnlx=1111594837-E+6087YwRl6mPL+Tjs+9/g>.
[24] "One Size Does Not Fit All: The Promise of Pharmacogenomics," National Center for Biotechnology Information, *A Science Primer*, (rev 31 March 2004): 1-2, <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html>.
[25] Jackson, John H., William J. Davey, and Alan O. Sykes, Jr., *Legal Problems of International Economic Relations, Cases, Materials and Text*, 4th Edition, (St. Paul: West Group, 2002): 1-2.
[26] Nguyen, Thi C., "Seeds of Change," The Implications of Biotechnology Patents, 1 (Boston: Harvard University Press, Spring 1996).
[27] Kaltenheuser, Skip, "Patents, Why Change A System That Fuels Invention?," *Los Angeles Times*, 12 October 1997. It was James Madison and the framers of the Constitution who reasoned that the U.S. government should grant the creator of an invention an exclusive property right for a limited but definite period of time, currently 20 years from the date of application. Upon grant, all patent details would become public knowledge. After the term expires everyone can freely use the

invention. The details of nearly 6 million inventions are now available to everyone, and the world's economy sails on the wind of ideas conceived in the U.S.

[28] Fieger, Jason F., "Patent Issues in Biotech – An Overview of Process and Law," Presentation to the Industrial College of the Armed Forces, Ft. McNair, Washington DC, 10 February 2005. The PTO fulfills a useful and necessary range of services designed to: (a) Grant patents for the protection of inventions and to register trademarks; (b) Serves the interests of inventors and businesses with respect to their inventions and corporate products, and service identifications; (c) It also advises and assists the bureasus and offices of the Department of Commerce and other agencies of the Government in matters involving IP such as patents, trademarks and semiconductor mask works; (d) Through preservation, classification, and dissemination of patent information, the office aids and encourages innovation and the scientific and technical advancement of the nation…". "In discharging its patent related duties, the Patent and Trademark Office examines applications and grants patents on inventions when applicants are entitled to them; it publishes and disseminates patent information, records assignments of patents, maintains search files of U.S. and foreign patents, and maintains a search room for public use in examining issued patents and records. It supplies copies of patents and official records to the public. Similar functions are performed relating to trademarks." Slides 3-4. "A patent is a right, granted by the government, that excludes others from making, using, or selling the invention covered in the claims of the patent. Only certain things can be patented. These are: new and useful processes, machines, manufactures, or compositions of matter, or any new and useful improvements thereof. Things that cannot be patented include: methods of doing business, processes composed only of mental steps, and mathematical formulae. Most new devices and machines can be patented. Software is patentable, so long as it falls within the proper categories set forth above." Slide 8.

[29] Linkkila, Timothy P. and Timothy E. Tracy, "Biotechnology Process Patents: Is Special Legislation Needed?," Franklin Pierce Law Center, 1 <http://www.fplc.edu/RISK/vol5/spring/lin&trac.htm>.

[30] Rai, Arti K. and Rebeccas S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *Law and Contemporary Problems* 66, no. 1 (2002): 3-4.

[31] Fieger, Slides 31-32.

[32] Jackson, 925.

[33] Ibid, 926 "Discrimination has been prohibited by a number of international agreements through the years, including to a degree the national treatment obligation of the General Agreement on Tariffs and Trade (GATT, Article III) and the Uruguay Round Agreement on Trade Related Aspects of Intellectual Property (WTO TRIPS Agreement)."

[34] Nestle, Marion, *Safe Food, Bacteria, Biotechnology, and Bioterrorism*, (Los Angeles: University of California Press, 2004): 226-228.

[35] French, Howard, "Whose Patent Is It, Anyway?," *New York Times* (5 March 2005), 2.

[36] French, 2.

[37] Ibid, 3.

[38] Sharma, Ashok B., "New Amendments to Patents Act, 1970 to Affect Farm Sector," The Financial Express, 3 January 2005 <http://www.financialexpress.com>.

[39] Bellman, Eric, "India Senses Patent Appeal," *The Wall Street Journal*, 11 January 2005, 20. "India's previous patent system, which allowed pharmaceutical companies to copy drugs patented abroad by just changing their manufacturing process, was aimed at keeping medicines inexpensive in India. It also allowed a local pharmaceuticals industry to thrive. By copying drugs other companies spent millions of dollars to develop, Indian pharmaceuticals companies could sell them at as little as on-tenth their original prices…. The new patent protections also are expected to result

in millions of dollars of new foreign investment in research out-sourcing in India…. With the stronger patent protection, more international companies will use India's relatively inexpensive engineers, scientists… for development and clinical testing…."
[40] Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," Washington, DC, October 2003, 12.
[41] U.S. Department of Energy, Office of Science, Genome Program, Human Genome Project Information, March 2005, <http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml>.

[42] MacDonald, Chris, and Rabul K. Dhauda, "Ethics in Biotechnology-An Executive Guide," 2003, Version 1.0, <www.guidingicarus.com>.
[43] PEW Initiative on Food and Biotechnology, "U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food," August 2003, 7, <http://pewagbiotech.org/>.
[44] Ibid.
[45] "Greek Medicine."
[46] http:www.ornl.gov/sci/techsources/Human_Genome/medicine/genetest.shtml
[47] Ibid.
[48] U.S. Department of Energy, Office of Science, Genome Program, Human Genome Project Information, "Genetics Privacy and Legislation", March 2005, 1, <http:ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml>.
[49] Ibid.
[50] Ibid.
[51] http://www.economist.com?PrinterFriendly.cfm?Story_ID=568825
[52] Ibid.
[53] Ibid.
[54] Ibid.
[55] Ibid.
[56] http//www.actionbioscience.org/genomic/barash.html
[57] Ibid.
[58] Ibid.
[59] "Biotechnology Industry Facts."
[60] Sevier, E. Dale and Dahms, A. Stephen, "The Role of Foreign Worker Scientists in the U.S. Biotechnology Industry," Nature Biotechnology, 20 no. 9 (2002): 955-956, <http://www.nature.com/cgi-taf/DynaPage.taf?file=/nbt/journal/v20/n9/full/nbt0902-955.html> (accessed 12 March 2005).
[61] Marshall, Michael L., Timothy Coffey, Fred E. Saalfeld, and Rita Colwell, "The Science and Engineering Workforce and National Security," Center for Technology and National Security Policy, National Defense University, *Defense Horizons*, 39, April 2004; and The National Science Foundation, "The Science and Engineering Workforce: Realizing America's Potential," National Science Board Report, NSB 03-69, December 2003.
[62] Frauenheim, Edward, "H1B Visa Limit for 2005 Already Reached," CNET Networks, Inc., 1 October 2004, <http://news.com.com/H-1B+visa+limit+for+2005+already+reached/2100-1022_3-5392917.html?tag=nefd.top> (accessed 12 March 2005).
[63] Dahms, A. Stephen, "Importance of H-1B Visa Holders to the U.S. Biotechnology Industry—A Study of San Diego and the Nation," BIOCOM San Diego Workforce Committee, 15 April 2000, <http://www.csuchico.edu/csuperb/WkFcSurvResults3.html> (accessed 12 March 2005).
[64] The National Nanotechnology Initiative, <http://www.nano.gov> (accessed 6 February 2005).

[65] Roco, Mihail C., "Converging Science And Technology At The Nanoscale: Opportunities For Education And Training," *Nature Biotechnology*, 21 no. 10 (October 2003): 1247-1249.
[66] Whitesides, George M., "The 'Right' Size in Nanobiotechnology," Nature Biotechnology, 21 no. 10 (October 2003): 1161-1165.
[67] Ibid.
[68] Editorial, "Why Small Matters," *Nature Biotechnology*, 21 no. 10 (October 2003): 1113.
[69] Seeman, Nadrian C., "Nanotechnology and the Double Helix," *Scientific American*, (June 2004): 64-75.
[70] Ibid.
[71] "Nanotechnology: Shaping the World Atom By Atom," Report of the National Science and Technology Council, Committee on Technology, The Interagency Working Group on Nanoscience, Engineering, and Technology, Washington, D.C., September 1999.
[72] "Why Small Matters."
[73] Baker.
[74] "Why Small Matters."
[75] "Farming for Pharmaceuticals", Mark Lesney, *Today's Chemist At Work*, 13, no.11, November 2004, <http://newfirstsearch.oclc.org>.
[76] Boston Business Journal, "Study: Nearly 50 new biotech medicines in pipeline", 2005-03-07.
[77] Bandow, Doug, "Demonizing Drugmakers, The Political Assault on the Pharmaceutical Industry", Policy Analysis, No. 475, Cato Institute, May 8, 2003, p. 5.
[78] Ibid., p. 5.
[79] Bandow, Doug, "Healers Under Siege", Cato Institute, July 11, 2003, <http://www.cato.org/research/articles/bandow-030711.html>.
[80] Bandow, Doug, "Demonizing Drugmakers, The Political Assault on the Pharmaceutical Industry", Policy Analysis, No. 475, Cato Institute, May 8, 2003, p. 9.
[81] Ibid., p. 10.
[82] Ibid., p. 5-6.
[83] Ibid., p. 14.
[84] The USDA now uses the term Genetically Enhanced (GE) in lieu of Genetically Modified (GM). However, for consistency purposes with current literature, this paper uses GM.
[85] James, Clive; Executive Summary, Preview Global Status of Commercialized Biotech/GM Crops: 2004, International Service for the Acquisition of Agri-biotech Applications.
[86] U.S. Department of Agriculture, Economic Research Service, Data, "Adoption of Genetically Engineered Crops in the U.S.," 27 July 2004.
[87] Ibid.
[88] "BIO Editors' and Reporters' Guide 2004-2005", *Agricultural Production Applications*, (June 2004): 90.
[89] Dry, Lisa, "Q&A with BIO Ag Chair Richard Hamilton," Biotechnology Industry Organization, 2005, <http://www.bio.org/news/features/20040129.asp?p+yes&>.
[90] Ibid.
[91] Cohen, Bonner R, "Proving A Negative: The Precautionary Principle at Odds with Science," *Objective Science: A Rational Foundation for the Sciences*, August 2001, <http://www.objectivescience.com/articles/hl_precaution.htm>.
[92] PEW Initiative, page 10.
[93] U.S. Department of State, "Announcement of U.S. Request for Dispute Panel in WTO Challenge to EU Biotech Moratorium," 7 August 2003, <www.state.gov>.
[94] PEW Initiative, page 12.

[95] Ibid.
[96] Einsiedel, Edna, "Consumers and GM Food Labels: Providing Information or Sowing Confusion?" *AgBioForum*, 3 no. 4 (2000), <http://www.agbioforum.org/v3n4/v3n4a09-einsiedel.htm>.
[97] Osborn, Alan, "EU Moves Forward with GM Food Despite Opposition," 22 February 2005, <www.checkbiotech.org>.
[98] Ibid.
[99] Ibid.
[100] "Brussels calls for risk analysis of GM ingredients," 30 March 2005, <www.checkbiotech.org/>.
[101] O'Toole, Tara and Thomas V. Inglesby, "Editorial: Toward Biosecurity," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1 no. 1 (2003) <www.biosecurity.org> (accessed 15 March 2005).
[102] Central Intelligence Agency, "The Darker Bioweapons Future," (OTI SF 2003-108), 3 November 2003.
[103] Alibek, Ken, with Stephen Handelman, *BioHazard*, (New York: Random House, 1999): 132-133.
[104] Ibid.
[105] Kyl, Jon, "S.15 – The Project Bioshield Act of 2004," Legislative Notice No. 67, 19 May 2004, <www. Thomas.com> (accessed 5 November 2004).
[106] Gottron, Frank, "*Project BioShield – CRS Report to Congress*," Congressional Research Service, The Library of Congress, Updated 3 August 2004.
[107] Gilfillan, Lynn et al, "Taking the Measures of Countermeasures: Leaders' Views on the Nation's Capacity to Develop Biodefense Countermeasures." *BioSecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 2 no. 4 (2004): 1-3, (Published online: 12 October 2004), <www.biosecurity.org> (accessed 9 November 2004).
[108] U.S. Congress, "Bioshield II: Biological, Chemical and Radiological Weapons Countermeasures Research Act," S-666, 19 March 2003.
[109] Institute of Medicine, *Protecting Our Forces: Improving, Vaccine Acquisition and Availability in the U.S. Military, e*dited by Lemon, Stanley et al, (Washington: National Academy Press, 2002): 9.
[110] Ibid, 56.
[111] Department of Defense Directive 6205.3 "DOD Immunization Program for Biological Warfare Defense," November 1993, <http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf>.
[112] "Vaccines the Sticking Point of Force Protection," Center for Technology and National Security Policy, National Defense University Conference 17 March 2005.
[113] Implemented in 2003 by the Department of Homeland Security, Project BioWatch is a detect-to-warn, environmental biodetection system. As the largest status quo bioagent detection capability in the U.S., it monitors for bioagents via a nationwide grid of air sampling devices and routine analysis.
[114] The CDC has also submitted an FY2005 initiative called BioSurveillance that advertises filling the gap between bioagent surveillance and early warning. This initiative will work to provide earlier indication of an attack through data sharing between health databases, expanded port of entry quarantine facilities, and an expansion of the Laboratory Response Network[114] to include food and animal diagnostics labs.
[115] Sosin, Daniel M., "Syndromic Surveillance: The Case for Skillful Investment," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1 no. 4 (2003): 247-253.

[116] Ibid. See also: Reingold, Arthur, "If Syndromic Surveillance Is The Answer, What Is The Question?" *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1 no. 2 (2003); Henning, Kelly J., "What is Syndromic Surveillance?" (Reports from a National Conference, 2003.) Center for Disease Control *Morbidity and Mortality Weekly Report*, 53 (24 September 2004) <www.cdc.gov> (accessed 17 March 2005).
[117] Ibid, Reingold, 77; Henning, 7.
[118] Sosin, 247.
[119] Hecht, Barbara K., and Frederick Hecht, eds., "Research with Red Tide Toxin Yields Potential Therapies for Cystic Fibrosis," MedicineNet.com, 19 November 2004, <http://www.medicinenet.com/script/main/art.asp?articlekey=40721>.
[120] "Scientists create 'fatherless' mouse," Ananova Press Release, 2005, <http://www.ananova.com/news/story/sm_929961.html?menu=news.scienceanddiscovery.amazingscience>.
[121] Penn State University, "Microbial Fuel Cell Cleans, Generates Electricity From Domestic Wastewater," 23 February 2004, <http://www.psu.edu/ur/2004/microbfuel.html>.
[122] Summers, Adam, American Museum of Natural History, "BioMechanics: Got Silk?," July-August 2001, <http://biomechanics.bio.uci.edu/_html/nh_biomech/gotsilk/spider_silk.htm>.
[123] Steinberg, Peter, et al, "Novel coatings for biofilms control and bioremediation," Environmental Biotechnology Cooperative Research Centre, <http://www.ebcrc.com.au/project4.htm>.
[124] Zhangliang, Chen, "Unlimited Prospects for Biotechnology," Knowledge Economy (Zhishi Jingji) (December 1999): 9, <http://www.usembassy.china.org.cn/sandt/biotech.html>.
[125] "Asia-Pacific Biotechnology Sectors," *MERGENT: A Company and Industry Analysis* (December 2004):19, <http://webreports.mergent.com>.
[126] Ibid, 7.
[127] Ibid, 19.
[128] "China's biotechnology industry," 14 May 2003, 1, <http://asia.proquestreference.com/pqasia>; and "Overseas Capital Taps Biotech Industry," Global News Wire-Asia Africa Intelligence Wire, 21 January 2005, 1, <http://web.lexis-nexis.com/universe/document?_m=6e6c89603f1055954136ab97fc1901>.
[129] "Asia-Pacific Biotechnology Sectors," 20.
[130] "China's biotechnology industry," 1; and Zhenzhen, Li, Zhang Jiuchun, Wen Ke, Halla Thorsteindottir, Uyen Quach, Peter S. Singer and Abdallah S. Daar, "Health biotechnology in China-reawakening of a giant," *Nature Biotechnology*, 22 (December 2004): DC15.
[131] Editors' and Reporters' Guide: Biotechnology Industry Organization 2004-2005, (Washington DC: Blue House Publishing, 2004):3.
[132] "China's biotechnology industry," 1.
[133] "Biotech's yin and yang; Chinese biotechnology," *The Economist*, 14 December 2002, 2; and Editors' and Reporters' Guide, 3; and Zhenzhen, DC15.
[134] Zhenzhen, DC17.
[135] Borrell, Jerry, "Asia has Strong Interest in Biotech, But No Infrastructure." *Venture Capital Journal*, 1 January 2005, 3, <http://proquest.umi.com/pqdweb?index=17&did=772137621&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111869513&clientId=3921>.
[136] Ibid, 4.
[137] Zhenzhen, DC14.

[138] Gargan, Edward A., "China Resumes Control of Hong Kong, Ending 156 Years of British Rule," *New York Times*, 1 July 1997, <http://www.nytimes.com/specials/hongkong/070197hongkong.html>. (accessed 10 April 2005).
[139] "Shanghai (Z. J.) Hi-Tech Park--one of China's national development zones," <http://www.shme.com/intro/zone/zone1.htm> (accessed 10 April 2005).
[140] Gwynne, Peter, "Asian tiger pounces on life sciences to replace departing high-tech manufacturing," *Research Technology Management*, 46 no. 3, (May/June 2003): 2.
[141] Barraclough, Emma, "The Rise and Rise of Bioscience," *Managing Intellectual Property*, 142 (September 2004): 73.
[142] "GlaxoSmithKline completes S$100mil Singapore expansion," *EDB Singapore*, 23 June 2004. <http://www.sedb.com/edbcorp/sg/en_uk/index/in_the_news/2003/2004/glaxosmithkline_completes.html> (accessed 22 March 2005).
[143] "Singapore's biomedical sciences industry recorded exceptional 33% growth in manufacturing output for 2004," Economic Development Board of Singapore, 31 January 2005.
[144] "Singapore 2005 Pharma output to level off," Drug Researcher.com, 1 March 2005.
[145] Theseira, Luanne, "Market Research-Singapore-Biotechnology," U.S. Commercial Service, U.S. Department Commerce, 7 June 2001.
[146] "Biotechnology Industry Facts."

BIBLIOGRAPHY

"2005 Investment Climate Statement – China," US China Embassy Website, <http://www.usembassy-china.org.cn/econ/021705inv.html>.

"A Survey of the Use of Biotechnology in U.S. Industry," U.S. Department of Commerce, Technology and Administration, Bureau of Industry and Security, October 2003.

Abate, Tom, "Tough Call-- Biotech- Data Responsibility vs. Public's Right to Know Scientist concerned sharing information could be dangerous", July 2000, <www.sfgate.com>.

Agency for Science Technology and Research, <http://www.a-star.edu.sg/astar/biopolis/index.do>.

"Agricultural Biotechnology Withering on the Vine, Says CSPI: Analysis Finds Fewer Biotech Crops Moving Through Regulatory System," CSPI Newsroom, Center for Science in the Public Interest, 2 February 2005, <http://cspinet.org/new/200502021.html>.

"Agriculture Bonds India, China," Global News Wire –Asia Africa Intelligence Wire, 23 March 2005, <http://web.lexis-nexis.com/universe/document?_m=2bd5ce8671af6fd280be89cb7555771b7>.

Alamy, "An overdose of bad news", *The Economist*, 17 March 2005.

Alibek, Ken, with Stephen Handelman, *BioHazard*, (New York: Random House, 1999): 132-133.

"America's next ethical war", *The Economist*, 12 April 2001, http://www.economist.com/PrinterFriendly.cfm?Story_ID=568825 >.

"An Evaluation of China's Science &Technology System and its Impact on the Research Community Environment," US China Embassy Website, <http://www.usembassy-china.org.cn/sandt>.

"Announcement of U.S. Request for Dispute Panel in WTO Challenge to EU Biotech Moratorium," 7 August 2003, <http://www.state.gov/e/eb/rls/othr/23109.htm>.

Anti-Cocaine Vaccine Produces Antibodies and Is Shown To Be Safe In Phase 1 Study Conducted By Yale Researcher. <http://www.yale.edu/opa/newsr/00-03-07-01.all.html>.

Anton, Philip S., Richard Silbeglitt, and James Schneider, "The Global Technology Revolution: Bio/Nano/Material Trends and Their Synergies with Information Technology by 2015," RAND National Defense Research Institute, Prepared for The National Intelligence Council, 2001.

"Are you wearing GM cotton?" *The Ecologist* 35 (February 2005): 9.

Armstrong, Robert, Patricia Coomber, and Stephen Prior with Ashley Dincher, "Looking for Trouble: A Policymaker's Guide to Biosensing," Center for Technology and National Security

Policy, National Defense University, June 2004.

Atkinson, Robert D., "The New Economy Labor Market," Industrial College of the Armed Forces Distinguished Lecture Program, Fort Lesley J. McNair, Washington, D.C., 10 February 2005.

"Asia-Pacific Biotechnology Sectors," *MERGENT: A Company and Industry Analysis* (December 2004) <http://webreports.mergent.com>.

Baker, Stephen, and Aston, Adam, "The Business of Nanotech," *BusinessWeek*, 14 February 2005, 65-71.

Bandow, Doug, "Demonizing Drugmakers, The Political Assault on the Pharmaceutical Industry," The Cato Institute, *Policy Analysis* no. 475 (8 May 2003).

Bandow, Doug, "Healers Under Siege," The Cato Institute, 11 July 2003, <http://www.cato.org>.

Bandow, Doug, "Punishing Drugmakers for Doing Good," 19 December 2004, <http://www.cato.org/pub_display.php?pub_id=2916>.

Bandow, Doug, "Saving Pfennige, Costing Lives," 17 March 2005, <http://www.cato.org/pub_display.php?pub_id=3710>.

Barasch, Carol Isaacson, "Ethical Issues in Pharmacogenetics", February 2001, <www.actionbioscience.org>.

Barraclough, Emma, "The Rise and Rise of Bioscience," *Managing Intellectual Property*, 142 (September 2004): 73.

Barrett, Jennifer, "The Challenge is to Stay Vigilant," *Newsweek Web Exclusive*, 6 February 2004, <http//msnbc.msn.com/id/4185431/print/1/displaymode/1098/> (accessed 29 March 2005).

"Barroso Commission recognizes contribution of biotech crops to European," 22 March 2005 <www.checkbiotech.org>.

Baumol, William J. and Alan S. Blinder, Economics: Principles and Policy, 9th Edition, (Mason: South-Western Publishing, 2003).

Bellman, Eric, "India Senses Patent Appeal," *Wall Street Journal*, 11 January 2005.

Bessin, Ric, "Bt-Corn: What it is and How it Works," University of Kentucky Entomology, University of Kentucky College of Agriculture, January 2004, <http://www.uky.edu/Agriculture/Entomology/entfacts/fldcrops/ef130.htm>.

"Better dead than GM-fed?" *The Economist*, 19 September 2002, <http://www.economist.com/displaystory.cfm?story_id=S%27%29H%20%2FQ%21%3F%2A%200%21D%0A>.

Bill Summary and Status for the 108th Congress, 2005, <http://thomas.loc.gov> (accessed 11 March 2005).

"BIO Editors' and Reporters' Guide 2004-2005", *Agricultural Production Applications*, (June 2004): 90.

"Biogen execs reaped millions before FDA report, Company denies employees knew of safety concerns before trades," 28 February 2005, <http://www.msnbc.msn.com/id/7048136/>.

"Biotech Country Overview," *Asia Private Equity Review*, 1 October 2003, Centre for Private Equity Research.

"Biotech in post-TRIPS India," *Nature Biotechnology* 23 (January 2005): 18-19.

"Biotech rice to get nod for commercial production," *China View*, <http://www.chinaview.cn>.

"Biotech Upturn," *New Scientist* , 5 (Jan 2005): 22-28.

"Biotech's yin and yang; Chinese biotechnology," *The Economist*, 14 December 2002, 87.

Biotechnology Industry Organization, "Agricultural Production Applications," June 2004, <http://www.bio.org/speeches/pubs/er/agriculture.asp?p=yes&>.

Biotechnology Industry Organization, "Biotechnology Industry Facts," June 2004, <http://www.bio.org/speeches/pubs/er/statistics.asp> (accessed 12 March 2005).

Biotechnology Industry Organization, "Biotechnology's Impact on Society", 1999, <http://www.accessexcellence.org/RC/AB/IE/Biotechnologys_Impact.html>.

"Biotechnology Industry Organization Editors' and Reporters' Guide 2004-2005: Agricultural Production Applications," June 2004, <http://www.bio.org/speeches/pubs/er/BiotechGuide.pdf>.

Biotechnology Industry Organization, "Facts and Fiction About Plant and Animal Biotechnology," June 2004, <http://www.bio.org/foodag/facts.asp?p=yes&>.

Biotechnology Industry Organization, "Frequently Asked Questions On Agricultural Biotechnology," June 2004, <http://www.bio.org/foodag/faq.asp?p=yes&>.

Borrell, Jerry, "Asia has Strong Interest in Biotech, But No Infrastructure." *Venture Capital Journal*, 1 January 2005, <http://proquest.umi.com/pqdweb?index=17&did=772137621&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111869513&clientId=3921>.

Brantley, David, "Singapore's Biomedicine Initiative: Prescription for Growth?" White Paper, 21 July 2004,

<http://www.technology.gov/reports/techpolicy/p_Singapore_Biomedical_2002.htm#III> (accessed 2 April 2005).

Breithaupt, Holger, *"China's leap forward in biotechnology,"* EMBO reports, *4 no. 2 (2003): 111-113,* <http://emboreports.npgjournals.com/cgi/content/full/4/2/111>.

BRI, The Institute, <http://www.ust.hk/~bri/fund.html> (accessed 10 April 2005).

Broad, William J. and Judith Miller, "Health Data Monitored for Bioterror Warning," *The New York Times*, 27 January 2003.

Brookes, Peter, "A Bad Idea Whose Time Has Come: The Lifting of the EU Arms Embargo on China," The Heritage Foundation, WebMemo #672, <http://www.heritage.org/Research/AsiaandthePacific/wm672.cfm>.

Brower, Vicki, "Biotech Embraces Bioethics", June 1999, <www.BioSpace.com>.

Brown, Eric, "Brave New China: The dangerous mixture of tyranny and biogenetics," *The Weekly Standard*, 23 September 2002, 26-28.

"Brussels calls for risk analysis of GM ingredients," 30 March 2005, <www.checkbiotech.org/>.

Buehler, James W. with Ruth L. Berkelman, David M. Hartley, and Clarence J. Peters, "Syndromic Surveillance and Bioterrorism-related Epidemics," Centers for Disease Control and Prevention. *Emerging Infectious Diseases*, 9 no. 10, October 2003, <www.cdc.gov> (accessed 17 March 2005).

Bush, George W., "Strengthening the International Regime against Biological Weapons," President's Statement on Biological Weapons, 1 November 2001, <www.state.gov> (accessed 15 March 2005).

"California gives go-ahead to stem-cell research," 3 November 2004, <http://www.msnbc.msn.com/id/6384390/> (accessed 2 April 2005).

Carafano, James J, "Improving the Federal Response to Catastrophic Bioterrorist Attacks: The Next Steps," The Heritage Foundation, *Backgrounder* 1705 (2003).

Carter, Colin A., and Guilluame P. Gruere, "Mandatory Labeling of Genetically Modified Foods: Does it Really Provide Consumer Choice?" *AgBio Forum* 6 no. 1&2 (2003), <http://www.agbioforum.org/v6n12/v6n12a13-carter.htm>.

Centers for Disease Control and Prevention, "CDC Role in Homeland Defense," briefing by Dr. Donald L. Noah, LTC, USAF, Centers for Disease Control and Prevention, Atlanta, GA., 4 March 2005.

Centers for Disease Control and Prevention, "Enhanced Surveillance Project (ESP)," CDC Emergency Preparedness and Response, <www.cdc.gov> (accessed 17 March 2005).

Centers for Disease Control and Prevention, "National Electronic Disease Surveillance System (NEDSS)", <www.cdc.gov> (accessed 17 March 2005).

Centers for Disease Control and Prevention, "The Laboratory Response Network: Bioterrorism Preparedness and Response System," Briefing at the Centers for Disease Control and Prevention, Atlanta, GA, 4 March 2005.

Central Intelligence Agency, "The Darker Bioweapons Future," (OTI SF 2003-108), 3 November 2003.

Central Intelligence Agency, World Fact Book: China, <http://www.cia.gov/cia/publications/factbook/geos/ch.html>.

Chien, Kenneth and Luther Chien, "The new Silk Road," *Nature*, 428 (11 March, 2004): 208-209.

"China: Conflicting pressures plague biotech policy," Oxford Research, 10 September 2004, <http://proquest.umi.com/pqdweb?index=41&did=758451511&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111870317&clientId=3921>.

"China planning large-scale introduction of genetically engineered rise," AFX News Limited, 30 November 2004, <http://web.lexis-nexis.com/universe/document?_m=cdbad9dd794c670f7888306d8a1ef77f>.

"China's biotechnology industry," 14 May 2003, <http://asia.proquestreference.com/pqasia>.

"China's Biotechnology Industry: Status and Prospects," HOBE Corporation, Paper prepared for INSS at National Defense University, February 2005.

"China's Economic, Social Development Plan," BBC Monitoring, 15 March 2005, *ISI Emerging Markets* online, <http://site.securities.com/doc.html?pc=cn&print=1&doc_id=7037626> (accessed 1 April 2005).

"China's Evolving Biotech Policy," US China Embassy Website, January 2000, <http://www.usembassy- china.org.cn/sandt/seedlaw.htm>.

"China's Small and Medium Enterprises: Room to Grow with WTO," US China Embassy Website, <http://www.usembassy-china.org.cn/econ/smes2002.html>.

"China's WTO Implementation: An Assessment of China's Third Year of WTO Membership," US-China Business Council, 7 September 2004, <http://uschina.org/public/documents/2004/09/tpsc_testimony.pdf>.

"Chinese more aware of dangers of genetically modified food: Greenpeace," *AFP Beijing*, 14 March 2005.

Chyba, Christopher F., "Toward Biological Security." *Foreign Affairs*, 81 issue 13 (May-June 2002).

Clayton, Mark, "Now, bioengineered trees are taking root; Transgenic poplars could make China a big player in lumber. But some experts worry about effects on nature.," *The Christian Science Monitor*, 10 March, 2005, 14-15.

Clive, James, "Preview Global Status of Commercialized Biotech/GM Crops: 2004, International Service for the Acquisition of Agri-biotech Applications," Executive Summary.

"Cocaine Vaccine; Ethical issues regarding cocaine vaccine outlined." *Obesity, Fitness & Wellness Week*, 16 October 2004, 321.

Cohen, Bonner R, "Proving A Negative: The Precautionary Principle at Odds with Science," *Objective Science: A Rational Foundation for the Sciences*, August 2001, <http://www.objectivescience.com/articles/hl_precaution.htm>.

Cohen, Joel, "Poorer nations turn to publicly developed GM crops," *Nature Biotechnology* 23 (January 2005): 27-33.

Conko, Gregory, "The Benefits of Biotech," *Regulation* (Spring 2003):20-25, <http://www.cato.org/pubs/regulation/regv26n1/v26n1-4.pdf>.

Cortright, Joseph, and Heike Mayer, "Signs of Life. The Growth of Biotechnology Centers in the U.S.," The Brookings Institution, Center on Urban and Metropolitan Policy, June 2002.

Council for Biotechnology Information, "Biotech Acres: Global Biotech Plantings Show Double-Digit Growth for Ninth Straight Year," 2004, <www.whybiotech.com>.

Dahms, A. Stephen, "Importance of H-1B Visa Holders to the U.S. Biotechnology Industry—A Study of San Diego and the Nation," BIOCOM San Diego Workforce Committee, 15 April 2000, <http://www.csuchico.edu/csuperb/WkFcSurvResults3.html> (accessed 12 March 2005).

DeFrancesco, Laura, "Little Science, Big Bucks," *Nature Biotechnology*, 21 no. 10 (October 2003): 1127-1129.

Dennis, Carina, "China: Stem cells rise in the East," *Nature*, 419 (26 September 2002): 334-336.

Department of Defense Directive 6205.3 "DOD Immunization Program for Biological Warfare Defense," November 1993, <http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf>.

Dratwa, Jim, "Taking Risks with the Precautionary Principle," *Science, Technology and Innovation Viewpoints*, <http://www.cid.harvard.edu/cidbiotech/comments/comments94.htm>.

Dry, Lisa, "Q&A with BIO Ag Chair Richard Hamilton," Biotechnology Industry Organization, 2005, <http://www.bio.org/news/features/20040129.asp?p+yes&>.

Early Aberration Reporting System (EARS), Centers for Disease Control and Prevention, Emergency Preparedness and Response, <www.cdc.gov> (accessed 28 March 2005).

Editorial, "Why Small Matters," *Nature Biotechnology*, 21 no. 10 (October 2003): 1113.

Editors' and Reporters' Guide: Biotechnology Industry Organization 2004-2005, (Washington DC: Blue House Publishing, 2004).

Einhorn, Bruce, "Hanging Hong Kong's Future on ..Biotech?" *Business Week Online Asia*, 18 March 2002, <http://www.businessweek.com/print/bwdaily/dnflash/mar2002/nf20020318_0352.htm?db> (accessed 10 April 2005).

Einsiedel, Edna, "Consumers and GM Food Labels: Providing Information or Sowing Confusion?" *AgBioForum*, 3 no. 4 (2000), <http://www.agbioforum.org/v3n4/v3n4a09-einsiedel.htm>.

Emanuel, Ezekiel J., Chief, Center for Clinical Bioethics, Session 2, Regulation 6: Institutional Review Boards (IRBs), Transcript: Sixth Meeting of the Philadelphia Council for Business Economics, 12 September 2004, <http://www.bioethics.gov/transcripts/sep02/session2.html>.

Epstein, Gerald L, Testimony before the Bioterrorism and Public Health Preparedness Subcommittee on Health, Education, Labor and Pensions, United States Senate, "Biodefense: Building a Medical Countermeasure Capability," 8 February 2005.

"EU project publishes conclusions and recommendations on GM foods," 6 January 2005, <www.etransfood.com>.

"Europe's food agency clears first GM sweetcorn for cultivation," 7 March 2005, <www.truthabouttrade.org>.

Fauci, Anthony S, Hearing before the Subcommittee on Bioterrorism and Public Health, Committee on Health, Education, Labor and Pensions, United States Senate, "The NIH Biodefense Research Program," 8 February 2005, <www://hhs.gov/asl/testify/t050208.html> (accessed 29 March 2005).

Fauci, Anthony, "An Expanded Biodefense Role for the National Institutes of Health," April 2002, <http://www.homelandsecurity.org/journal/Articles/fauci.htm> (accessed 29 March 2005).

Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," Washington, DC, October 2003.

Fernandez-Cornejo, Jorge, "Data: Adoption of Genetically Engineered Crops in the U.S.," US Dept of Agriculture Economic Research Service, 27 July 2004, <http://www.ers.usda.gov/Data/BiotechCrops/>.

Fernandez-Cornejo, Jorge, "Genetically Engineered Crop Varieties Gain Further Acreage Share in 2004," *Amber Waves* (September 2004) <www.ers.usda.gov/publications/ah717>.

Fernandez-Cornejo, Jorge, USDA Economic Research Service, "Data: adoption of genetically engineered crops in the U.S.," last updated 27 July 2004, <http://www.ers.usda.gov/Data/BiotechCrops/>.

Fieger, Jason F. "Patent Issues in Biotech–An Overview of Process and Law," Presentation to the Industrial College of the Armed Forces, Ft. McNair, Washington DC, 10 February 2005.

Frank, Mitch, "Stem-Cell Struggles," *Time* 165, no. 13 (2005):17, <http://www.time.com/time/archive/printout/0,23657,1039706,00.html>.

Frauenheim, Edward, "H1B Visa Limit for 2005 Already Reached," CNET Networks, Inc., 1 October 2004, <http://news.com.com/H-1B+visa+limit+for+2005+already+reached/2100-1022_3-5392917.html?tag=nefd.top> (accessed 12 March 2005).

French, Howard, "Whose Patent Is It, Anyway?," *New York Times* (5 March 2005): 2.

"Frequently-Asked Questions," Biotechnology Project, Center for Science in the Public Interest, 8 April 2005, <http://cspinet.org/biotech/faq.html>.

Gale, Fred, William Lin, Bryan Lohmar and Francis Turn, "Is Biotechnology in China's Future," Economic Research Service, China's Food and Agriculture: Issues for the 21st Century/AIB-775, 34-37.

Gargan, Edward A., "China Resumes Control of Hong Kong, Ending 156 Years of British Rule," *New York Times*, 1 July 1997, <http://www.nytimes.com/specials/hongkong/070197hongkong.html>. (accessed 10 April 2005).

Geng, Xiao, "Sustainable Growth," *Far Eastern Economic Review*, January/February 2005, 54-55.

Gerberding, Julie H., Hearing before the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, United States Senate, "CDC's Terrorism and Global Disease Detection Efforts," 28 April 2004, <http://www.hhs.gov/asl/testify/t040428b.html> (accessed 2 April 2005).

"Geron and Hong Kong's Biotechnology Research Corporation Form Strategic Alliance for Telomerase Activation Therapies," Geron Corporation Press Release, 2 March 2, 2005, <http://biz.yahoo.com/bw/050302/16320_1.html> (accessed 10 April 2005).

Gieringer, Dale H., "The Safety and Efficacy of New Drug Approval," *Cato Journal* (Spring/Summer 1985): 177-201. <http://cato.org/pubs/journal/cj5n1/cj5n1-10.pdf>.

Gilboy, George J, "The Myth Behind China's Miracle," *Foreign Affairs* (July/August 2004): 33-48.

Gilfillan, Lynn et al, "Taking the Measures of Countermeasures: Leaders' Views on the Nation's Capacity to Develop Biodefense Countermeasures." *BioSecurity and Bioterrorism:*

Biodefense Strategy, Practice, and Science, 2 no. 4 (2004): 1-3, (Published online: 12 October 2004), <www.biosecurity.org> (accessed 9 November 2004).

"GlaxoSmithKline completes S$100mil Singapore expansion," *EDB Singapore*, 23 June 2004, <http://www.sedb.com/edbcorp/sg/en_uk/index/in_the_news/2003/2004/glaxosmithkline_completes.html> (accessed 22 March 2005).

Global Knowledge Center on Crop Biotechnology, "Questions and Answers about Genetically Modified Crops," International Service for the Acquisition of Agri-Biotech Applications, February 2005, <www.isaaa.org>.

"GM foods", *The Economist*, <www.economist.com>, January 2005.

"GM Foods: Where are we now?" October 2004, <www.which.net/campaign>.

Goldberg, Joseph E., "Future Technologies in the Area of Biodefense." Delivered at Biotech India 2005 2nd International Exhibition and Conference on Biotechnology, New Delhi, India, 9 February 2005.

Goldenberg, Norman S. and Peter Tenen, *Casenote Legal Briefs, Patent Law, (*Santa Monica: Casenotes Publishing Co., Inc., 1998).

Goldstein, Morris, "Adjusting China's Exchange Rate Polices," Institute for International Economics, paper presented at the International Monetary Fund seminar on China's Foreign Exchange Rate System, Dalian, China 26-27 May 2004, <http://www.iie.com/publications/wp/2004/wp04-1.pdf>.

Gottron, Frank, "*Project BioShield – CRS Report to Congress*," Congressional Research Service, The Library of Congress, Updated 3 August 2004.

"Gov't to Develop Biotech," Chinese Internet Information Center, 26 July 2004, <http://asia.proquestreference.com/pqasia>.

Grace, Eric S., *Biotechnology Unzipped Promises& Realities*, (Washington: Joseph Henry Press, 1997).

Graham, Judith and Ronald Kotulak, "Bioterror Research Goes High-Tech, Focuses on Earlier Warnings," *SunHerald.com*, 8 April 2004.

Graham, Sarah, "Squid may inspire new nanolights", *ScientificAmerican.com*, Science News, 9 January 2004, <http://www.sciam.com/article.cfm?chanID=sa003&articleID=000D6161-DE4E-1FFD-974E83414B7F00FF>.

"Greek Medicine," National Institute of Health, 16 September 2002, <http://www.nlm.nih.gov/hmd/greek/greek_oath.htlm>.

Grubb Philip, "Review of Intellectual Property Rights and the Life Science Industries: A Twentieth Century History by Graham Dutfield," *Nature Biotechnology*, 21 (December 2004): 1439-1440.

Gwynne, Peter, "Asian tiger pounces on life sciences to replace departing high-tech manufacturing," *Research Technology Management*, 46 no. 3, (May/June 2003): 2.

Hale, David and Lyric Highes Hale, "China Takes Off," *Foreign Affairs* (November/December 2003): 36-53.

Hanan, Sher, "Is Small Beautiful?" *The Jerusalem Report*, *23* August 2004, 30 <http://proquest.umi.com.ezproxy6.ndu.edu/pqdweb?index=0&did=688555141&SrchMode=1&sid=4&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1113174331&clientId=3921>.

Health and Human Services, "Budget in Brief for FY 2006." Centers for Disease Control and Prevention Overview, pages 34-45, <www.hhs.gov/budget> (accessed 17 March 2005).

Hecht, Barbara K., and Frederick Hecht, eds., "Research with Red Tide Toxin Yields Potential Therapies for Cystic Fibrosis," MedicineNet.com, 19 November 2004, <http://www.medicinenet.com/script/main/art.asp?articlekey=40721>.

Henderson, David, "Hidden Drug-Reimport Potential", *The Washington Times*, February 2004.

Henning, Kelly J., "What is Syndromic Surveillance?" (Reports from a National Conference, 2003.) Center for Disease Control *Morbidity and Mortality Weekly Report*, 53 (24 September 2004) <www.cdc.gov> (accessed 17 March 2005).

Hepeng, Jia, "China steps towards international M&A," *Nature Biotechnology*, 23 (February 2005): 159.

Hilleman, Maurice, "Vaccines and the Vaccine Enterprise: Historic and Contemporary View of Scientific Initiative of Complex Dimensions", *The Jordan Report Accelerated Development of Vaccines 2002*, NIAID, 2002.

Hong Kong Institute of Biotechnology, Ltd., <http://www.hkib.org.hk/aboutus/aboutus.html> (accessed 10 April 2005).

Hong Kong Jockey Club, <http://www.hkjc.com/english/charity/trust_donations_medical.htm> (accessed 10 April 2005).

Holman, Craig A. and Kara L. Daniels, "Safety Act reduces Contractors' Liability Risks Associated With Qualified Antiterrorism Technologies," *Analysis & Perspective* 78 no. 23 (2002).

Hossain, Ferdaus and Carl E. Pray, Yanmei Lu, Jijun Huang, et al., "Genetically Modified Cotton and Farmers' Health in China," *International Journal of Occupational and Environmental Health*, 10 no. 3, (July-September 2004): 296-304,

<http://proquest.umi.com/pqdweb?index=53&did=697416241&SrchMode=1&sid=14&Fmt=4&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111870510&clientId=3921>.

Hsiao, Jamese C. and Kenneth Fong, "Making big money form small technology," *Nature*, 428 (11 March 2004): 218-220.

Hsu, Spencer, Jamie Stockwell, and Fred Barbash, "Initial Pentagon Test is Positive for Anthrax," *The Washington Post*, 15 March 2005, <http://www.washingtonpost.com/wp-dyn/articles/A35943-2005Mar15.html> (accessed 15 March 2005).

Huang, Alice Shih-hou, "Follow your nose," *Nature*, 428 (11 March 2004): 221-222.

Huang, Jikin and Quifang Wang, "Agricultural Biotechnology Development and Policy in China," Chinese Academy of Sciences, <http://www.agbioforum.org/v5n4/v5n4a01-huang.htm>.

Huang, Jikun and Ruifu Hu, Qinfang Wang, James Keeley and Jose Zepeda, "Agricultural Biotechnology Development, Policy, and Impacts in China," Center for Chinese Agricultural Policy, Chinese Academy of Sciences.

Huang, Jikun, and Scott Rozelle, Carl Pray, and Qinfang Wang, "Plant Biotechnology in the Developing World: The Case of China," Biotechnology Research Institute, Chinese Academy of Agricultural Sciences, 6 September 2001.

Hudgins, Edward L., "Perspectives," *Regulation* 20, no. 1 (21 January 2005): 1-17, <http://www.cato.org/pubs/regulation/reg20n1-per.html>.

Hufbauer, Gary Clyde and Yee Wong, "China Bashing 2004," International Institute of Economics, International Economics Policy Briefs, Number PB04-05, September 2004, <http://www.iie.com/publications/pb/pb04- 5.pdf>.

"Human Embryonic Stem Cell Research in China," US China Embassy Website, September 2002, <http://www.usembassy-china.org.cn/sandt/stemcell.htm>.

Hutchings, Robert L., National Intelligence Council, "Mapping the Global Future: A Report of the National Intelligence Council's 2020 Project," December 2004.

Hutwagner, Lori and Timothy Browne, G. Matthew Seeman, and Aaron T. Fleischauer, "Comparing Aberration Detection Methods with Simulated Data," Centers for Disease Control and Prevention, *Emerging Infectious Diseases*, 11 no. 2 (February 2005) <www.cdc.gov> (accessed 28 March 2005).

Hyde, Honorable Henry J, "Hong Kong, China, and the World," The Heritage Foundation, Heritage Lecture #862 <http://www.heritage.org/Research/AsiaandthePacific/hl862.cfm>.

"India, China to emphasize GM technology," *International News on Fats, Oils, and Related Materials: INFORM*, 15 no. 12, December 2004, 787,

<http://proquest.umi.com/pqdweb?index=21&did=769200021&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111869827&clientId=3921>.

Institute of Medicine, *Giving Full Measures to Countermeasures*, edited by Joellenbeck, Lois; Durch, Jane; and Benet, Leslie, (Washington: National Academy Press, 2004).

Institute of Medicine, *Protecting Our Forces: Improving, Vaccine Acquisition and Availability in the U.S. Military, e*dited by Lemon, Stanley et al, (Washington: National Academy Press, 2002): 9.

"International Agreements: The WTO and the Biosafety Protocol," *AgBiotech Buzz: World of Food*, 4 issue 3, <http://pewbiotech.org>.

"IPR Strategy to Define Government's Role," Chinese Internet Information Center, 14 June 2004, <http://asia.proquestrefrence.com/pqasia>.

Isla, Damian, "Robotuna Project To Model Real Fish," 17 October 1995, <http://www-tech.mit.edu/V115/N49/robotuna.49n.html>.

Jackson, John H., William J. Davey, and Alan O. Sykes, Jr., *Legal Problems of International Economic Relations, Cases, Materials and Text*, 4th Edition, (St. Paul: West Group, 2002).

James, Clive, "Preview: Global Status of Commercialized Biotech/GM Crops: 2004 (Executive Summary)," International Service for the Acquisition of Agri-Biotech Applications, <www.isaaa.org>.

Jarvis, Lisa, "Mining Biotechnology Opportunity in China," *Chemical Market Reporter*, 28 June 2004, 6, <http://proquest.umi.com/pqdweb?index=55&did=660660141&SrchMode=1&sid=14&Fmt=4&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111870854&clientId=3921>.

Jayaraman, K.S, "Indian Bt gene monoculture, potential time bomb," *Nature Biotechnology*, 23 (February 2005): 159.

Jonietz, Erika, "generic biotech," *Technology Review*, 107 no. 10, (December 2004): 54-59, <http://proquest.umi.com/pqdweb?index=25&did=745333041&SrchMode=1&sid=14&Fmt=4&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111870112&clientId=39210>.

Kalaitzandonakes, Nicholas, "Another Look at Biotech Regulation," *Regulation* 27, no. 1 (Spring 2004): 44-50, <http://www.cato.org/pubs/regulation/regv27n1/v27n1-5.pdf>.

Kaltenheuser, Skip, "Patents, Why Change A System That Fuels Invention?" *Los Angeles Times*, 12 October 1997.

Kapp, Robert A., "China's Progress in Implementing It's WTO Accession Commitments," US-China Business Council, Oral remarks by President of the US-China Business Council to the Trade Policy Staff Committee Hearing 23 September 2004, <http://uschina.org/public/documents/2004/09/tpsc_remarks.html>.

Kass, Leon R., *Toward a More Natural Science*, (New York: The Free Press, 1985): 224-246.

Kilpatrick, Robert, "Global BioPartnering: A Personal Perspective," *Biopharm International* 17 (May 2004): 30-32, <http://proquest.umi.com/pqdweb?index=66&did=638868211&SrchMode=1&sid=14&Fmt=4&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111870948&clientId=3921>.

King, David A., "The scientific impact of nations: What different countries get for their research spending," *Nature*, 439 (15 July 2004): 311-316.

Kumar, Nandini, Uyen Quach, Halla Thorsteinsdottir, Hemlatha Somsekhar, Abdallah S. Daar and Peter A. Singer, "Indian biotechnology-rapidly evolving and industry fed," *Nature Biotechnology*, 22 (December 2004): DC31-36.

Kwik, Gigi, Joe Fitzgerald, Thomas V. Inglesby, and Tara O'Toole, "Biosecurity: Responsible Stewardship of Bioscience in an Age of Catastrophic Terrorism," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 1 no. 1 (2003):27-35.

Kyl, Jon, "S.15 – The Project Bioshield Act of 2004," Legislative Notice No. 67, 19 May 2004, <www.Thomas.com> (accessed 5 November 2004).

Lague, David, "The Promise of Food Security," *Far Eastern Economic Review*, 4 April 2002, 34-37.

Lane, H. Clifford, John La Montagne, and Anthony Fauci, "Bioterrorism: A clear and present danger," *Nature Medicine* 7 no. 12 (2001): 1271-1273.

Lardy, Nicholas, "Chinese Wages and Exports," International Institute of Economics, testimony before the Senate democratic Policy Committee Hearing, 29 March 2004, <http://www.iie.com/publications/papers/lardy0304-tables.pdf>.

Larmer, Brook and John Ness, "Mad Science; The far-out advances won't come in the West, but in places where cloning and gene manipulation inspire little debate," *Newsweek* (International edition) 16 September 2002, 84.

Lawrence, Stacy, "A banner biotech year in 2004," *Nature Biotechnology*, 23 (February 2005): 164.

Leadbetter, Ron, "Asclepius," Encyclopedia Mythica, 3 March 1997, <http://www.pantheon.org/articles/a/asclepius.html>.

Leavitt, Michael O., Secretary, Department of Health and Human Services. "The President's FY2006 Budget for HHS," Testimony before House Committee on Appropriations. Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, 3 March 2005, <www.hhs.gov> (accessed 17 March 2005).

Lesney, Mark, "Farming for Pharmaceuticals," *Today's Chemist At Work*, 13 no.11 (November 2004) <http://newfirstsearch.oclc.org>.

Levine, Henry, Hearing on China and WTO: Assessing and Enforcing Compliance, U.S.- China Economic and Security Review Commission, US Department of Commerce, <http://www.export.gov/china/assisting_us_exporters/levinetestimony.asp>.

Lewis, Raphael and Michael Levenson, "Govenor Concedes Defeat on Stem-Cell Bill: Raises Possibility of US Legislation," *The Boston Globe*, 2 April 2005, <http://www.boston.com/news/local/massachusetts/articles/2005/04/02/romney_concedes_defeat_on_stem_cell_research/>.

Liebowitz, Stan J. and Stephen E. Margolis, *The Economics of QWERTY: Theory, History and Policy*. (New York: New York University Press and London: Palgrave Publishing, 2001).

Lim, Lisa P., Michael J. Gregory, "Singapore's Biomedical Science sector development strategy: Is it sustainable?" *Journal of Commercial Biotechnology*, 10 no 4, (June 2004): 352.

Linkkila, Timothy P. and Timothy E. Tracy, "Biotechnology Process Patents: Is Special Legislation Needed?" Franklin Pierce Law Center, <http://www.fplc.edu/RISK/vol5/spring/lin&trac.htm>.

Li, Shaomin, "Corruption by Design: Building Clean Government in Mainland China," *Far Eastern Economic Review*, March 2005, 68-71.

"Life sciences company to acquire Shanghai- based Bio Asia," *Health & Medicine Week*, 10 January, 2005, 894, <http://proquest.umi.com/pqdweb?index=10&did=774779271&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111869513&clientId=3921>.

Lombardo, Joseph S., H. Burkom, J. Pavlin, "Essence II and the Framework for Evaluating Syndromic Surveillance Systems," *MMWR Supplement* (24 September 2004) <www.cdc.gov> (accessed 28 March 2005).

Loonsk, John W., "BioSense: A National Initiative for Early Detection and Quantification of Public Health Emergencies," Centers for Disease Control and Prevention, *MMWR Supplement* (24 September 2004) <www.cdc.gov> (accessed 29 March 2005).

Lotus-Effect, Nees Institute for Biodiversity of Plants, <http://www.botanik.uni-bonn.de/system/lotus/en/lotus_effect_multimedia.html>.

MacDonald, Chris and Rahul K. Dhanda, 2003, "Ethics in Biotechnology- An Executive Guide (version 1.0), <www.guidingicarus.com>.

Mahley, Donald A., Ambassador, Acting Deputy Assistant Secretary of State for Multilateral and Conventional Arms Control, "U.S. Views on Disease Surveillance," Statement to the Annual Meeting of Experts for the Biological Weapons Convention (BWC), 19-30 July 2003, Geneva, Switzerland, dated 4 August 2004, <www.state.gov> (accessed 15 March 2005).

Mahley, Donald A., U.S. Special Negotiator for Chemical and Biological Arms Control Issues. Statement by the U.S. to the Ad Hoc Group of BWC States Parties, Geneva, Switzerland, 25 July 2001, <http://www.state.gov>.

Mandl, Kenneth D., et al., "Implementing Syndromic Surveillance: A Practical Guide Informed by the Early Experience," *Journal of the American Medical Informatics Association*, 11 no. 2 (March/April 2004).

Mapping the Global Future, Report of the National Intelligence Council's 2020 Project, (Washington, D.C.: Government Printing Office, December 2004).

Marchant, Gary E., "Two Problems with the Precautionary Principle," *Science, Technology and Innovation Viewpoints*, <http://www.cid.harvard.edu/cidbiotech/comments/comments90.htm>.

Marris, Emma, "DNA gets a fake fifth base," 16 March 2005, <http://www.nature.com/news/2005/050314/full/050314-8.html>.

Marshall, Michael L., Timothy Coffey, Fred E. Saalfeld, and Rita Colwell, "The Science and Engineering Workforce and National Security," Center for Technology and National Security Policy, National Defense University, *Defense Horizons*, 39, April 2004.

Mazzola, Laura, "Commercializing Nanotechnology," *Nature Biotechnology*, 21 no. 10 (October 2003): 1137-1143.

McGee, Marianne Kolbasuk, "IBM Debuts Bio-Surveillance Software," *InformationWeek* (8 February 2005) <www.informationweek.com> (accessed 28 March 2005).

"Mergers and Acquisitions; Life sciences company to acquire Shanghai- based Bio Asia," *Obesity, Fitness & Wellness Week*, 15 January 2005, 910, <http://proquest.umi.com/pqdweb?index=6&did=774783771&SrchMode=1&sid=12&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111868547&clientId=3921>.

Moodie, Michael (with Jonathan Ban, Catherine Manzi, and Michael J. Powers), *Bioterrorism in the United States: Threat, Preparedness, and Response* (Washington: Chemical and Biological Arms Control Institute, 2000).

Murphy, David, "China Uncorks the Gene in the Bottle," *Far Eastern Economic Review*, 22, March 2001.

"Nanotechnology: Shaping the World Atom By Atom," Report of the National Science and Technology Council, Committee on Technology, The Interagency Working Group on Nanoscience, Engineering, and Technology, Washington, D.C., September 1999.

National Academy of Sciences. Executive Summary to: *Microbial Threat to Health: Emergence, Detection, and Response*. NAS, 2003, <www.nap.edu> (accessed 17 March 2005).

National Intelligence Council, "Report of the National Intelligence Council's 2020 Report", December 2004, 34.

National Research Council, *Biotechnology Research in an Age of Terrorism*, (Washington: The National Academies Press, 2004).

Naughton, Barry, "An Economic Bubble? Chinese Policy Adapts to Rapidly Changing," *China Leadership Monitor*, 6 (Spring 2003), <http://www.chinaleadershipmonitor.org/20041/bn.pdf>.

Naughton, Barry, "Cooling the Chinese Economy: Urgent: How to Handle an Overheated Economy," *Foreign Policy* (November/December 2004): 64-68.

Nestle, Marion, *Safe Food, Bacteria, Biotechnology, and Bioterrorism*, (Los Angeles: University of California Press, 2004).

New Delhi PTI News Agency, "India calls for global monitoring body to tackle bio-terrorism," 2 March 2005, <http://www.fbis.gov/portal/server.pt/gateway/PTARGS_0_1518_215_240_0_43/> (accessed 23 March 2005).

"New MS drug pulled after patient death: Tysabri's withdrawal from market deflates hopes for treatment," 28 February 2005, <http://www.msnbc.msn.com/id/7045585>.

Nguyen, Thi C., "Seeds of Change," The Implications of Biotechnology Patents, 1 (Boston: Harvard University Press, Spring 1996).

Normille, Dennis, "Can Money Turn Singapore into a Biotech Juggernaut?" *Science*, 297 no 5586, (30 August 2002): 1470.

North, Michael, "Greek Medicine "I swear by Apollo Physician…" Greek Medicine from the Gods to Galen", *National Library of Medicine*, 2002.

"Novartis Sets Up TB, Dengue Centre," DrugResearcher.com, 5 July 2004.

Odessey, Bruce, "Swiftly Expanding U.S.-China Economic Relations Stir Debate: Fastest-growing export market also accounts for biggest trade deficit," US China Embassy Website, 16 March 2005, <http://www.usembassy-china.org.cn/press/release/2005/031605swi.html>.

Office of the Secretary of Defense, "Military Transformation a Strategic Approach", Fall 2003, <http://www.oft.osd.mil/library/library_files/document_297_MT_StrategyDoc1.pdf>.

Office of the U.S. Trade Representative and the U.S. Department of Agriculture, "Announcement of U.S. Request for Dispute Panel in WTO Challenge to EU Biotech Moratorium," 7 August 2003, <http://www.state.gov/e/eb/rls/othr/23109.htm>.

Office of the U.S. Trade Representative press release, "U.S. and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Foods and Crops," 13 May 2003, <www.ustr.gov/releases/2003/05/03-31.htm>.

Office of the U.S. Trade Representative, European Communities - Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291,292,and 293), "Comments of the

United States on the EC's Responses to the Questions Posed by the Panel after the Second Substantive Meeting," 18 March 2005, <http://www.ustr.gov/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/WTO/Dispute_Settlement_Index_-_Pending.html>.

Office of the U.S. Trade Representative, European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291,292,and 293), "Executive Summary of U.S. Opening Statement on Expert Issues at the second Substantive Meeting, 23 March 2005, <http://www.ustr.gov/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/WTO/Dispute_Settlement_Index_-_Pending.html>.

Office of the U.S. Trade Representative, European Communities – Measures Affecting the Approval and Marketing of Biotech Products (WT/DS291,292,and 293), "Response of the United States to the Request for a Preliminary Ruling Submitted by the European Communities," 24 March 2005, <http://www.ustr.gov/Trade_Agreements/Monitoring_Enforcement/Dispute_Settlement/WTO/Dispute_Settlement_Index_-_Pending.html>.

Office of the US Trade Representative Press Release, "U.S. and Cooperating Countries File WTO Case Against EU Moratorium on Biotech Foods and Crops," 13 May 2003, <www.ustr.gov/releases/2003/05/03-31.htm>.

"One Size Does Not Fit All: The Promise of Pharmacogenomics," National Center for Biotechnology Information, *A Science Primer*, (rev 31 March 2004): 1-2, <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html>.

Oppenheimer, Andy, "Researching the weapons of the future: genetically modified bioweapons," Abstract, Janes Information Group, 14 September 2004, <http://www.janes.com/security/international_security/news/jcbw/jcbw040914_1_n.shtml> (accessed 2 April 2005).

Osborn, Alan, "EU Moves Forward with GM Food Despite Opposition," 22 February 2005, <www.checkbiotech.org>.

O'Toole, Tara and Thomas V. Inglesby, "Editorial: Toward Biosecurity," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1 no. 1 (2003) <www.biosecurity.org> (accessed 15 March 2005).

"Overseas Capital Taps Biotech Industry," Global News Wire-Asia Africa Intelligence Wire, 21 January 2005, <http://web.lexis-nexis.com/universe/document?_m=6e6c89603f1055954136ab97fc1901>.

"Owning the body and the soul", *The Economist*, 10 March 2005 <http://www.economist.com/displaystory.cfm?story_id=S%27%29%280%2FRQ%5F%22%21%40%23%24%0A>.

Paris AFP, "Interpol calls for greater pooling of information as bioterrorism summit closes," 2 March 2005, <http://www.fbis.gov/portal/server.pt/gateway/PTARGS_0_1518_215_240_0_43/>

(accessed 23 March 2005).

Paris Radio France Internationale, "France Proposes Database To Track Bioterror Threat," 2 March 2005, <http://www.fbis.gov/portal/server.pt/gateway/PTARGS_0_1518_215_240_0_43/> (accessed 23 March 2005).

Partos, Lindsey, "European Commission Takes Stock of GM Food Ingredients," 22 March 2005, <http://www.foodproductiondaily.com/>.

Paull, Robert, et al., "Investing in Nanotechnology," *Nature Biotechnology*, 21 no. 10 (October 2003): 1144-1147.

Penn State University, "Microbial Fuel Cell Cleans, Generates Electricity From Domestic Wastewater," 23 February 2004, <http://www.psu.edu/ur/2004/microbfuel.html>.

Peterson, Peter G, "Riding for A Fall," *Foreign Affairs* (September/October 2004): 111-127.

PEW Initiative on Food and Biotechnology, "Is Labeling GM Foods an Effective Means of Facilitating Choices for Consumers?" *AgBiotech Buzz: Labeling GM Foods*, 2 issue 8 (28 August 2002) <http://pewagbiotech.org/buzz/>.

PEW Initiative on Food and Biotechnology, "U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food," August 2003, <http://pewagbiotech.org/>.

"Pharma R&D: Next Big Thing in Jobs," *The Economic Times Online*, 2 July 2004, <http://economictimes.indiatimes.com>.

Pollack, Andrew, "F.D.A. Issues a Guide to Gathering Genetic Data," *The New York Times* (23 March 2005): 1, <http://www.nytimes.com/2005/03/23/business/23pharma.html?adxnnl=1&adxnnlx=1111594837-E+6087YwRl6mPL+Tjs+9/g>.

Poo, Mu-ming, "Cultural reflections," *Nature*, 428 (11 March 2004): 204-205.

"Promoting Hi-tech in Hong Kong," Asian Technology Information Technology Information Program (ATIP), 24 June 1998, <http://www.atip.org/public/atip.reports.98/atip98.051r.html>.

Public Broadcast Station, "Avoiding Armageddon. Our Future. Our Choice. WMD: A Primer.," 4 April 2005, <http://www.pbs.org/avoidingarmageddon/learnTheFacts/learn_02_01_prolif.html> (accessed 14 March 2005).

Purvis, Nigel, "Building a Transatlantic Bioitech Partnership," *Issues in Science & Technology*, 21, issue 1 (Fall 2004) <http://search.epnet.com/login.aspx?direct=true&db=fth&an=14690068>.

Questions and Answers on the Regulation of GMOs in the European Union, 22 March 2005, <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTM >.

Questions and Answers on the Regulation of GMOs in the European Union, 22 March 2005, <http://europa.eu.int/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTM>.

Rai, Arti K. and Rebeccas S. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *Law and Contemporary Problems* 66, no. 1 (2002): 3-4, <http://www.law.duke.edu/journeals/66LCPRai>.

RAND Corp., "Syndromic Surveillance: An Effective Tool for Detecting Bioterrorism?" Center for Domestic and International Health Security, 2004, <www.rand.org> (accessed 17 March 2005).

Reichart, John, et al., "Toward a National Biodefense Strategy: Challenges and Opportunities," Center for Counterproliferation Research, National Defense University, April 2003.

Reingold, Arthur, "If Syndromic Surveillance Is The Answer, What Is The Question?" *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1 no. 2 (2003).

Rifkin, Jeremy, *The Biotech Century*, (New York: Penguin Putnam, Inc., 1998): 115.

Roco, Mihail C., "Converging Science And Technology At The Nanoscale: Opportunities For Education And Training," *Nature Biotechnology*, 21 no. 10 (October 2003): 1247-1249.

Rogatina, Anna, "Agricultural Education and the Precautionary Principle," *Science, Technology, and Innovation Viewpoints*, <http://www.cid.harvard.edu/cidbiotech/comments/comments88.htm>.

Ruffolo, Robert, "Discovery and development impacts on Pharma R&D," 16 March 2005, Keynote speech at the annual Drug Discovery Technology conference, <www.DrugResearcher.com>.

Santini, Laura, "Drug Companies Look to China for Cheap R&D," *Wall Street Journal* (Eastern edition), 22 November 2004, B1, <http://proquest.umi.com/pqdweb?index=27&did=740618621&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111870112&clientId=3921>.

Saywell, Trish, "Promising Prospects," *Far Eastern Economic Review*, 15 January 2005, 39.

Schuler, Ari, "Billions for Biodefense: Federal Agency Biodefense Funding, FY2001-FY2005," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 2 no. 2 (2004): 86-96 with Erratum.

"Scientists create 'fatherless' mouse," Ananova Press Release, 2005, <http://www.ananova.com/news/story/sm_929961.html?menu=news.scienceanddiscovery.amazingscience>.

"Scientists make salmon spawn trout," Ananova Press Release, 2005, <http://www.ananova.com/news/story/sm_1046156.html?menu=news.scienceanddiscovery.amazingscience>.

"Scientists Push GM Rice Commercialism," Global News Wire – Asia Africa Intelligence Wire, 8 June 2004, <http://web.lexis-nexis.com/universe/document?_m=csbad9dd794c670f7888306d8a1ef77f>.

Seeman, Nadrian C., "Nanotechnology and the Double Helix," *Scientific American*, (June 2004): 64-75.

Segal, Adam, "Is America Losing Its Edge?" *Foreign Affairs* (2004), <http://www.foreignaffairs.org/20041101facomment83601/adam-segal/is-america-losing-its-edge.html> (accessed 31 March 2005).

Sevier, E. Dale and Dahms, A. Stephen, "The Role of Foreign Worker Scientists in the U.S. Biotechnology Industry," *Nature Biotechnology*, 20 no. 9 (2002): 955-956, <http://www.nature.com/cgi-taf/DynaPage.taf?file=/nbt/journal/v20/n9/full/nbt0902-955.html> (accessed 12 March 2005).

"Shanghai (Z. J.) Hi-Tech Park--one of China's national development zones," <http://www.shme.com/intro/zone/zone1.htm> (accessed 10 April 2005).

Sharma, Ashok B., "Biotech Clocks 39% Growth", *The Financial Express* (4 April 2005) <http://www.financialexpress.com/>.

Sharma, Ashok B., "New Amendments to Patents Act, 1970 to Affect Farm Sector," *The Financial Express*, 3 January 2005 < http://www.financialexpress.com>.

Shelton, Jeffery, "Emerging Biotech Regulatory Policy,": The Industrial College of the Armed Forces Student Paper, Fort McNair, Washington DC, AY 2004-2005.

Silberman, Laurence H., and Charles S. Robb, et al, Report to the President of the United States, "The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction," 31 March 2005.

Simons, Craig, "Of Rice and Men; After years of indecision, China may soon let its farmers plant genetically modified strains of Asia's staple crop," *Newsweek*, 20 December 2004, 38, <http://proquest.umi.com/pqdweb?index=19&did=763810731&SrchMode=1&sid=14&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111869513&clientId=3921>.

"Singapore Pharmaceutical Output to be Flat," *Forbes.com*, 7 March 2005, <http://www.forbes.com/associatedpress/feeds/ap/2005/03/07/ap1865115.html>.

"Singapore's Man with a Plan," *The Economist*, 372 (14 August 2004): 60.

"Singapore's Pharma Sector Exceeds Aims," *Drug Researcher.com*, 2 January 2005 (accessed 3 April 2005).

Sitathan, Tony, "Singapore Takes Biomedical Road to Growth," *Asia Times online*, 9 July 2004, <http://www.atimes.com/atimes/Southeast_Asia/FG09Ae01.html> (accessed 29 March 2005).

"Small Wonders, Endless Frontiers: a Review of the National Nanotechnology Initiative," *Report of the National Research Council*, 2002, Executive Summary.

Smith, Bradley T., Thomas V. Inglesby, and Tara O'Toole, "Biodefense R&D: Anticipating Future Threats, Establishing a Strategic Environment," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 1 no. 3 (2003): 193-202.

Smith, Dale, Director Military History USUHS, "Vaccines the Sticking Point of Force Protection," Center for Technology and National Security Policy, National Defense University Conference, 17 March 2005.

Smith, Frances B., "Only One Side of the Risk Equation," International Consumers for Civil Society, <http://www.foodstuff.org/biotech/pp-fran.htm>.

Smith, Jeremy, "China Seen Opening Door Soon to Biotech Rice," *Science News Article*, 28 February 2005, <www.Reuters.com>.

Smith, Jeremy, "EU to Push Approving GMOs, Could Come in Few Weeks," 22 March 2005, <www.washingtonpost.com>.

Smith, Jeremy, "Lawmaking on Genetic (GMO) Food is Minefield for EU," 28 February 2005, <www.usatoday.com>.

Sosin, Daniel M., "Syndromic Surveillance: The Case for Skillful Investment," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 1 no. 4 (2003): 247-253.

"Southern comfort, eastern promise; Third-world biotechnology," *The Economist*, 11 December 2004, 83.

"Special Report: Hong Kong Emerging from the Global Biotech Map," *Asia Pacific Biotech News*, 8 no. 1, 2004, <http://www.asiabiotech.com> (accessed 10 April 2005).

Spencer, Jack, and Michael Scardaville, "Understanding the Bioterrorist Threat: Facts and Figures," The Heritage Foundation, *Backgrounder* 1488 (2001).

Stabinsky, Doreen, "Patents on Cells, Genes, and Organisms Undermine the Exchange of Scientific Ideas," *Chronicle for Higher Education* 45, issue 22, (1999) <http://www.gene-watch.org/programs/patents/undermine.html>.

Standard & Poor's Industry Surveys, *Biotechnology*, 23 December 2004, New York, NY.

Steinberg, Peter, et al., "Novel coatings for biofilms control and bioremediation," Environmental Biotechnology Cooperative Research Centre, <http://www.ebcrc.com.au/project4.htm>.

Stevenson-Yang, Anne, and Ken DeWoskin, "China Destroys The IP Paradigm," *Far Eastern Economic Review*, March 2005, 9-18.

Stoto, Michael A. and Matthias Schonlau, Louis T, Mariano, "Syndromic Surveillance: Is it Worth the Effort?", *Chance*, 17 no.1 (2004).

Strohm, Chris, "Congress seeks to stimulate market for bioagent vaccines," GovExec.com Daily Briefing, 16 December 2004, <http://www.govexec.com> (accessed 14 February 2005).

"Study finds biotech crops are being grown in 18 countries and researched in 45," Council for Biotechnological Information, 9 January 2005, <http://web.lexis-nexis.com/universe/document?_m=4395b14257c47ee747db56d8dff5306a>.

"Study: Nearly 50 new Biotech Medicines in Pipeline," *Boston Business Journal*, 7 March 2005.

Summers, Adam, American Museum of Natural History, "BioMechanics: Got Silk?," July-August 2001, <http://biomechanics.bio.uci.edu/_html/nh_biomech/gotsilk/spider_silk.htm>.

SYBASE, "An Overview of Syndromic Surveillance and the SYBASE Synsdromic Surveillance IT Architecture," White Paper, 2004, <www.sybase.com> (accessed 28 March 2005).

"The Celebrex case," The University of Rochester v. G.D. Searle.

The Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Washington, DC, October 2003.

"The Feynman Grand Prize for Theoretical and Experimental Molecular Nanotechnology," Foresight Institute, Palo Alto, CA, <http://www.foresight.org/> (accessed 31 March 2005).

"The Hong Kong Jockey Club," Answers.com, <http://www.answers.com/topic/hong-kong-jockey-club> (accessed 10 April 2005).

The National Nanotechnology Initiative, <http://www.nano.gov> (accessed 6 February 2005).

The National Science Foundation, "The Science and Engineering Workforce: Realizing America's Potential," National Science Board Report, NSB 03-69, December 2003.

The National Security Strategy of the United States of America, The White House, Washington DC, 17 September 2002, <http://www.whitehouse.gov/nsc/nss.html> (accessed 29 December 2004).

Theseira, Luanne, "Market Research-Singapore-Biotechnology," U.S. Commercial Service, U.S. Department Commerce, 7 June 2001.

"The Tiger in Front: A Survey of India and China," *Economist*, 5-11 March 2005, special insert, 1-16.

"The University of California v. Eli Lilly & Co.," Federal Circuit 1997.

The University of Texas at Austin. College of Engineering News Release, "Engineers Develop Biowarfare Sensing Elements That Permit Mass Production of Highly Sensitive and Stable Nerve-Gas Detectors," 10 February 2005,

<http://www.engr.utexas.edu/news/articles/20050210757/index.cfm> (accessed 14 February 2005).

Thorsteinsdottir, Halla, Uyen Quach, Abdallah S. Daar, and Peter A. Singer, "Conclusions: promoting biotechnology innovation in developing countries," *Nature Biotechnology*, 22 (December 2004): DC48-52.

Thorsteinsdottir, Halla, Uyen Quach, Douglas K. Martin, Abdallah S. Daar, and Peter A. Singer, "Introduction: promoting global health through biotechnology," *Nature Biotechnology*, 22 (December 2004): DC 3-7.

"Transgenic Tomato Developed to Fight Hepatitis B," *China Today*, 1 September 2004, <http://asia.proquestrefrence.com/pqasia>.

"Trouble in nanoland; Nanotechnology," *The Economist*, 7 December 2002, 107.

Tso, T.C., "Agriculture of the future," *Nature*, 428 (11 March 2004): 215-216.

U.S. Congress, "Bioshield II: Biological, Chemical and Radiological Weapons Countermeasures Research Act," S-666, 19 March 2003.

U.S. Congress, Office of Technology Assessment, "Biotechnology in a Global Economy," OTA-BA-494, U.S. Government Printing Office, Washington, D.C., October 1991, <http://www.wws.princeton.edu/~ota/ns20/year_f.html> (accessed 12 March 2005).

U.S. Congress, Senate, Democratic Policy Committee, "Chinese Wages and Exports," Testimony of Nicholas Lardy before the Senate, 29 March 2004, <http://www.iie.com/publications/papers/lardy0304-tables.pdf>.

U.S. Department of Agriculture, Economic Research Service, Data, "Adoption of Genetically Engineered Crops in the U.S.," 27 July 2004.

U.S. Department of Commerce, "A Survey of the use of Biotechnology in U.S. Industry," October 2003.

U.S. Department of Energy, Annual Energy Outlook for 2005, Report by the Energy Information Administration, Department of Energy, (Washington DC: Government Printing Office, February 2005).

U.S. Department of Energy, Office of Science, Genome Program, Human Genome Project Information, "Genetics Privacy and Legislation", March 2005, <www.Doegenomes.org>.

U.S. Department of Health and Human Services, "HHS Fact Sheet—Project Bioshield," 21 July 2004, <http://www.hhs.gov/news/press/2004pres/20040721b.html> (accessed 29 March 2005).

U.S. Department of Health and Human Services, Centers for Disease Control, "The Laboratory Response Network: Partners in Preparedness," 5 April 2005, http://www.bt.cdc.gov/lrn/pdf/lrnhistory.pdf> (accessed 29 March 2005).

U.S. Department of Homeland Security, "BioWatch, Early Detection, Early Response," 2005.

U.S. Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, "Inspection of the FBI's Security Risk Assessment Program for Individuals Requesting Access to Biological Agents and Toxins," March 2005.

U.S. Department of State, "Announcement of U.S. Request for Dispute Panel in WTO Challenge to EU Biotech Moratorium," 7 August 2003, <www.state.gov>.

U.S. Department of State, "U.S. Efforts to Combat the BW Threat," Fact Sheet, Released by the U.S. Delegation to the 5th BWC Review Conference, Geneva, Switzerland, 14 November 2002, <www.state.gov> (accessed 15 March 2005).

U.S. Department on Homeland Security, "Emergencies and Disasters. Prevention and Planning. National Response Plan.", December 2004, <http://www.dhs.gov/dhspublic/interapp/editorial/editorial_0566.xml (accessed 16 April 2005).

U.S. Government Printing Office, "Budget of the US Government FY2005," <http://www.gpoaccess.gov/usbudget/fy05/browse.html> (accessed 2 April 2005).

U.S. Office of Management and Budget, "FY06 Budget Priorities: Homeland Security," <http://www.whitehouse.gov/omb/pdf/Homeland-06.pdf> (accessed 2 April 2005).

U.S. Office of the National Counterintelligence Executive, "National Counterintelligence Strategy of the United States," March 2005.

U.S. Presidential Directive, "Biodefense for the 21st Century," 28 April 2004.

U.S. Supreme Court, *Diamond v. Chakrabarty, 447 U.S./ 303 (1980)*, <http://caselaw.lp.findlaw.com/scripts/getcase>.

UniGuide, Academic Guide to the Internet, <http://www.aldea.com/guides/ag/biotx.html> (accessed 12 March 2005).

"Vaccines the Sticking Point of Force Protection," Center for Technology and National Security Policy, National Defense University Conference 17 March 2005.

Vaidhyanathan, Siva, *The Anarchist in the Library*, (New York: Perseus Books Group, 2004).

Van Arnum, Patricia, "Demand for Innovative Drugs Rises in China," *Chemical Market Reporter*, 267, 17 January 2005, <http://proquest.umi.com/pqdweb?index=1&did=788218541&SrchMode=1&sid=4&Fmt=6&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111867370&clientId=3921>.

Van der Haegen, Tony, "EU View of Precautionary Principle in Food Safety," speech to American Branch of the International Law Association, 23-25 October 2003, <http://www.eurunion.org/News/speeches/2003/031023tvdh.htm>.

Walter, Katie, "When Semiconductors Go Nano," Lawrence Livermore National Laboratory, Chemistry and Materials Science Division, Livermore, CA, <http://www-cms.llnl.gov/s-t/nano-semiconductors.html> (accessed 31 March 2005).

Wang, Xueman, "Challenges and Dilemmas in Developing China's National Biosafety Framework," *Journal of World Trade*, 38 (October 2004): 899, <http://proquest.umi.com/pqdweb?index=6&did=751650171&SrchMode=1&sid=7&Fmt=3&VInst=PROD&VType=PQD&RQT=309&VName=PQD&TS=1111866947&clientId=3921>.

Weeden, Shelton, Li, and Hoffmann, eds, "Biological Control: A Guide to Natural Enemies in North America," Cornell University, <http://www.nysaes.cornell.edu/ent/biocontrol/pathogens/bacteria.html> (accessed 10 April 2005).

Wengei, Ding, "The Beauty of Science," *Beijing Review*, 26 August 2004, <http://asia.proquestrefrence.com/pqasia>.

Whitesides, George M., "The 'Right' Size in Nanobiotechnology," *Nature Biotechnology*, 21 no. 10 (October 2003): 1161-1165.

"Why China Gives Green Light to US GMOs," *Xinhua General News Service*, 3 May 2004, <http://web.lexis-nexis.com/universe/document?_m=f1e79c98867b81d25883bee63711a335>.

Williams, Patricia J., "Unnatural Acts," *The Nation*, (12 July 2004): 13.

Wolf, Charles, Jr., K.C. Yeh, Benjamin Zycher, Nicholas Eberstadt, and Sung-Ho Lee, "Fault Lines in China's Economic Terrain," *RAND Corporation*, Published report for the Office of Net Assessment, Washington DC., 2003.

Wolfe, Mitchell I., Kurt B. Nolte, and Steven S. Yoon, "Fatal Infectious Disease Surveillance in a Medical Examiner Database," Centers for Disease Control and Prevention, *Emerging Infectious Diseases*, 10 no. 1 (January 2004) <www.cdc.gov> (accessed 28 March 2005).

Wolfowitz, Paul, "Thinking About the Imperatives of Defense Transformation," Heritage Lecture #831, The Heritage Foundation, 30 April 2004, <www.heritage.org> (accessed 16 March 2005).

World Health Organization, "20 Questions on Genetically Modified (GM) Foods," <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.

World Health Organization, "A new threat...Global Alert and Response: Responding to Potential Intentional Use of Biological Agents", <www.who> (accessed 15 March 2005).

World Health Organization, "Containing Outbreaks in the field", <www.who> (accessed 15 March 2005).

World Health Organization, "Global Outbreak Alert and Response Network", <www.who> (accessed 15 March 2005).

"WTO Scorecard: China's Year-Three Commitments," The US-China Business Council, <http://uschina.org/public/documents/2005/01/wtoscorecard2004.pdf>.

Wu, Chung-I, Shuhua Shi and Ya-ping Zhang, "A case for conservation," *Nature*, 428 (11 March, 2004): 213-214.

Wu, Ray, "Making an impact," *Nature*, 428 (11 March, 2004): 206-207.

Yang Xiangzhong, "An embryonic nation," *Nature*, 428 (11 March 2004): 210-212.

Zaracostas, John, "China gains economic force," *The Washington Times*, 29 November 2004, <http://web.lexis-nexis.com/universe/document?_m=91ea990dd3b170f6e4f6f86230feb868>.

Zhangliang, Chen, "Unlimited Prospects for Biotechnology," Knowledge Economy (Zhishi Jingji) (December 1999), <http://www.usembassy.china.org.cn/sandt/biotech.html>.

Zhao, Jian-Zhao, Jun Cao,Yaxin Li, Hilda L. Collins, Richard T. Roush, Elizabeth D. Earle and Anthony M. Shelton, "Transgenic plants expressing two Bacillus thuringiensis toxins delay insect resistance evolution," *Nature Biotechnology*, 21 (December 2003): 1493-1497.

Zhenzhen, Li, Zhang Jiuchun, Wen Ke, Halla Thorsteindottir, Uyen Quach, Peter S. Singer and Abdallah S. Daar, "Health biotechnology in China-reawakening of a giant," *Nature Biotechnology*, 22 (December 2004): DC13-18.